



SALES BULLETIN #17

DATE: June 14, 2004
TO: Cephalon Sales Organization
FROM: Lauren Mangus
RE: PRIOR AUTHORIZATION GUIDE

The purpose of this bulletin is to inform you of the proper use of the PRIOR AUTHORIZATION GUIDE that was sent out to all field personnel last week.

- The PRIOR AUTHORIZATION GUIDE is intended as an educational tool only. It is not intended to be used as a promotional piece.
- You may photocopy the ICD-9 Code cards that are included in the PRIOR AUTHORIZATION GUIDE for both Sleep and Wakefulness Disorders and Pain Disorders. You may also print out copies of these ICD-9 codes from the PDF files that are being sent with this bulletin.
 - You may not modify the ICD-9 code listing.
 - If a physician asks about the appropriate code for a condition, you should advise the physician to refer to the table for the appropriate code. You should remind the physician that it is his or her responsibility to determine and submit an appropriate code.
 - You should never detail from the list of ICD-9 Codes or suggest coding to the physician or billing manager.

6/14/2004

SAL-BUL-04-017

PLAINTIFFS TRIAL
EXHIBIT
P-11460_00001

- Please refer to the attached Implementation Guides for further clarification.
- Copies of the ICD-9 codes for both Sleep and Wakefulness Disorders and Pain Disorders will be made available at Promotech for representatives to order. However, they are not currently stocked. Notification will be sent to the entire Sales Organization when the ICD-9 codes are available for ordering at Promotech. Please utilize photocopies of the PRIOR AUTHORIZATION GUIDE cards or the attached PDF files in the interim.

6/14/2004

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SAL-BUL-03-005

Sales Training Implementation Guide for ICD-9 Codes: Sleep Disorders

WHAT IS IT?

The attached table contains ICD-9 codes for "Dyssomnias" and "Sleep disorders associated with mental, neurological, or other medical conditions" as found in the International Classification of Sleep Disorders.

HOW IS IT USED?

These codes are used by physicians for describing diagnoses and procedures.

WHAT CAN I DO WITH IT?

- You may reprint this table and provide it to your physicians' offices.
- If a physician asks about the appropriate code for a condition, you should advise the physician to refer to the table for the appropriate code. You should remind the physician that it is his or her responsibility to determine and submit an appropriate code.
- You should never detail from the list of ICD-9 Codes or suggest coding to the physician or billing manager.
- **If a physician asks a question** about third party payor coverage policies and processes concerning on or off-label uses of Cephalon products, you may provide factual, accurate information about the third party payor's coverage policies and processes, including whether a particular use is covered by that payor, and provide contact information to enable the physician to directly contact the third party payor or the Cephalon sponsored reimbursement hotline. However, if the use inquired about is off-label, you must begin by clearly stating that our products are not approved by FDA for such uses and you may not recommend any unapproved uses of Cephalon products. Again, in no event may you advise or suggest that a particular code be used, even if you are aware that a payor has previously provided reimbursement under that code.

If a physician has additional questions, please refer them to Professional Services for more information.

ICD-9-CM Diagnosis Codes

DYSSOMNIAS		ICD-9 Codes	
Intrinsic Sleep Disorders			
Psychophysiological Insomnia	307.42-0	Extrinsic Sleep Disorders	
Sleep State Misperception	307.49-1	Inadequate Sleep Hygiene	307.41-1
Idiopathic Insomnia	780.52-7	Environmental Sleep Disorder	780.52-6
Narcolepsy	347	Altitude Insomnia	289
Recurrent Hypersomnia	780.54-2	Adjustment Sleep Disorder	307.41-0
Idiopathic Hypersomnia	780.54-7	Insufficient Sleep Syndrome	307.49-4
Post-traumatic Hypersomnia	780.54-8	Limit-setting Sleep Disorder	307.42-4
Obstructive Sleep Apnea Syndrome	780.53-0	Sleep-onset Association Disorder	307.42-5
Central Sleep Apnea Syndrome	780.51-0	Food Allergy Insomnia	780.52-2
Central Alveolar Hypoventilation Syndrome	780.51-1	Nocturnal Eating (Drinking) Syndrome	780.52-8
Periodic Limb Movement Disorder	780.52-4	Hypnotic-Dependent Sleep Disorder	780.52-0
Restless Legs Syndrome	780.52-5	Stimulant-Dependent Sleep Disorder	780.52-1
Intrinsic Sleep Disorder NOS	780.52-9	Alcohol-Dependent Sleep Disorder	780.52-3
		Toxin-Induced Sleep Disorder	780.54-6
		Extrinsic Sleep Disorder NOS	780.52-9
Circadian-Rhythm Sleep Disorder			
Time Zone Change (Jet Lag) Syndrome	307.45-0		
Shift Work Sleep Disorder	307.45-1		
Irregular Sleep-Wake Pattern	307.45-3		
Delayed Sleep-Phase Syndrome	780.55-0		
Advanced Sleep-phase Syndrome	780.55-1		
Non-24-Hour Sleep-Wake Disorder	780.55-2		
Circadian Rhythm Sleep Disorder NOS	780.55-9		

SLEEP DISORDERS ASSOCIATED WITH		ICD-9 Codes	
Mental Disorders			
Psychoses	290-319		
Mood Disorders	290-299		
Anxiety Disorders	296-301, 311		
Panic Disorders	300, 308, 309		
Alcoholism	300		
	303, 305		
Neurologic Disorders			
Cerebral Degenerative Disorders	320-389		
Dementia	330-337		
Parkinsonism	331		
Fatal Familial Insomnia	332		
Sleep-Related Epilepsy	337.9		
Electrical Status Epilepticus of Sleep	345		
Sleep-Related Headaches	345.8		
	346		
Other Medical Disorders			
Sleeping Sickness	086		
Nocturnal Cardiac Ischemia	411-414		
Chronic Obstructive Pulmonary Disease	490-496		
Sleep-Related Asthma	493		
Sleep-Related Gastroesophageal Reflux	530.81		
Peptic Ulcer Disease	531-534		
Fibromyalgia	729.1		

Updated: 10/21/2003

Sales Training Implementation Guide for ICD-9 Codes: Pain Disorders

WHAT IS IT?

The attached table contains ICD-9 codes for Pain as found in the International Classification of Pain Disorders.

HOW IS IT USED?

These codes are used by physicians for describing diagnoses and procedures.

WHAT CAN I DO WITH IT?

- You may reprint this table and provide it to your physicians' offices.
- If a physician asks about the appropriate code for a condition, you should advise the physician to refer to the table for the appropriate code. You should remind the physician that it is his or her responsibility to determine and submit an appropriate code.
- You should never detail from the list of ICD-9 Codes or suggest coding to the physician or billing manager.
- **If a physician asks a question** about third party payor coverage policies and processes concerning on or off-label uses of Cephalon products, you may provide factual, accurate information about the third party payor's coverage policies and processes, including whether a particular use is covered by that payor, and provide contact information to enable the physician to directly contact the third party payor or the Cephalon sponsored reimbursement hotline. However, if the use inquired about is off-label, you must begin by clearly stating that our products are not approved by FDA for such uses and you may not recommend any unapproved uses of Cephalon products. Again, in no event may you advise or suggest that a particular code be used, even if you are aware that a payor has previously provided reimbursement under that code.

If a physician has additional questions, please refer them to Professional Services for more information.

ICD-9-CM Diagnosis Codes

PAIN		ICD-9 Codes	
Abdominal	789.0	Growing	781.99
Adnexa (uteri)	625.9	Hand	729.5
Alimentary (due to vascular insufficiency)	557.9	Head	784.0
Anginoid	786.51	Heart	786.51
Anus	569.42	Infraorbital (see also Neuralgia)	350.1
Arch	729.5	Intermenstrual	625.2
Arm	729.5	Jaw	526.9
Back (postural)	724.5	Joint	719.40
(low)	724.2	Ankle	719.47
(psychogenic)	307.89	Elbow	719.42
Bile duct	576.9	Foot	719.47
Bladder	788.9	Hand	719.44
Bone	733.90	Hip	719.45
Breast	611.71	Knee	719.46
(psychogenic)	307.89	Multiple sites	719.49
Broad ligament	625.9	Pelvic region	719.45
Cartilage NEC	733.90	Psychogenic	307.89
Cecum	789.0	Shoulder (region)	719.41
Cervicobrachial	723.3	Specified site NEC	719.48
Chest (central)	786.50	Wrist	719.43
(atypical)	786.59	Kidney	788.0
(midsternal)	786.51	Laryngeal	784.1
(musculoskeletal)	786.59	Leg	729.5
(noncardiac)	786.59	Limb	729.5
(substernal)	786.51	Low back	724.2
wall (anterior)	786.52	Lumbar region	724.2
Coccyx	724.79	Mastoid	388.70
Colon	789.0	Maxilla	526.9
Common duct	576.9	Metacarpophalangeal (joint)	719.44
Costochondrial	786.52	Metatarsophalangeal (joint)	719.47
Diaphragm	786.52	Mouth	528.9
Due to presence of any device, implant or graft	996.0-996.5	Muscle	729.1
Ear	388.70	(intercostal)	786.59
Epigastric	789.06	Nasal	478.1
Extremity (lower) (upper)	729.5	Nasopharynx	478.29
Eye	379.91	Neck NEC	723.1
Face, facial	784.0	(psychogenic)	307.89
(atypical)	350.2	Nerve NEC	729.2
(nerve)	351.8	Neuromuscular	729.1
Female genital organ NEC	625.9	Nose	478.1
(psychogenic)	307.89	Ocular	379.91
Finger	729.5	Ophthalmic	379.91
Flank	789.0	Orbital region	379.91
Foot	729.5	Osteocopic	733.90
Gallbladder	575.9	Ovary	625.9
Gas (intestinal)	787.3	(psychogenic)	307.89
Gastric	536.8	Painful respiration	786.52
Generalized	780.99	Painful scar	709.2
Genital organ		Painful urination	788.1
(female)	625.9	Pelvic (female)	625.9
(male)	608.9	(male NEC)	789.0
(psychogenic)	307.89	(psychogenic)	307.89
Groin	789.0	Penis	607.9
		(psychogenic)	307.89

ICD-9-CM Diagnosis Codes (continued)

PAIN		ICD-9 Codes	
Pericardial	786.51	Seminal vesicle	608.9
Perineum		Sinus	478.1
(female)	625.9	Skin	782.0
(male)	608.9	Spermatic cord	608.9
Pharynx	478.29	Spinal root	729.2
Pleura, pleural, pleuritic	786.52	Stomach	536.8
Preauricular	388.70	(psychogenic)	307.89
Precordial (region)	786.51	Substernal	786.51
(psychogenic)	307.89	Temporomandibular (joint)	524.62
Psychogenic	307.80	Temporomaxillary joint	524.62
Cardiovascular system	307.89	Testis	608.9
Gastrointestinal system	307.89	(psychogenic)	307.89
Genitourinary system	307.89	Thoracic spine	724.1
Heart	307.89	(with radicular and visceral pain)	724.4
Musculoskeletal system	307.89	Throat	784.1
Respiratory system	307.89	Tibia	733.90
Skin	306.3	Toe	729.5
Radicular (spinal)	729.2	Tongue	529.6
Rectum	569.42	Tooth	525.9
Respiration	786.52	Trigeminal	350.1
Retrosternal	786.51	Umbilicus	789.05
Rheumatic NEC	729.0	Ureter	788.0
(muscular)	729.1	Urinary (organ) (system)	788.0
Rib	786.50	Uterus	625.9
Root (spinal)	729.2	(psychogenic)	307.89
Round ligament (stretch)	625.9	Vagina	625.9
Sacroiliac	724.6	Vertebrogenic (syndrome)	724.5
Sciatic	724.3	Vesical	788.9
Scrotum	608.9	Vulva	625.9
(psychogenic)	307.89	Xiphoid	733.90



SALES BULLETIN #16

DATE: May 24, 2004
TO: Sales & Marketing
FROM: Dana Luscombe
RE: Cephalon Speaker Bureau Changes

The Sales & Marketing teams have completed an extensive review of our Cephalon Speaker Bureau, after analyzing the results the Sales & Marketing teams are implementing the following changes to help structure, standardize, develop and qualify our Speaker Bureau.

The Speaker Bureau changes are categorized into four (4) sections:

1. Speaker Classifications
2. Speaker Honorarium
3. New Speaker Additions
4. Speaker Qualification Process

1. Speaker Classifications: - (see attachment for details)

The Speaker Classification categories have been streamlined from four (4) classifications (Approved, Consultant Speaker, Qualified, Prospect) to two (2) active classifications (Approved, Qualified). The historical Consultant Speaker and Prospect classifications have been re-classified as outlined below:

Consultant Speaker	---->	Qualified	
Prospect	---->	Qualified	- Has MEP(s) booked for 2004
	OR		
Prospect	---->	Nominee	- No MEP's booked for 2004

A third classification of "Nominee" is **only** viewable to the management team, speakers with a "Nominee" classification are pending qualification and are **not eligible** to speak at MEP's.

2. **Speaker Honorarium:** - (see attachment for details)

The Honorarium schedule has been adjusted for MEPs and Teleconferences and distinct payment tiers have been created between Approved and Qualified speakers. The goal is to motivate the Qualified speakers to become more knowledgeable and to incent Qualified speakers to move up the speaker hierarchy to become "Approved".

3. **New Speaker Additions:** - (see attachment for details)

There are new processes and controls for adding speakers to the Speaker Bureau. The process outlined below could take between two (2) and eight (8) weeks to get a speaker added so please plan accordingly:

- By the first of each month the Sales Specialist identifies potential new speaker(s) and forwards them to their Area Manager.
- The AM reviews the potential new speaker(s) and if appropriate will create a consolidated spreadsheet and forward to the MDM.
 - A new Excel Export Template named "**Speaker Nominee**" is available in SMART the next time you replicate, the template can be used to easily create the speaker add spreadsheet.
 - In SMART, select the potential speaker additions, click on the "Export to Excel" icon and select the "Speaker Nominee" template. Your spreadsheet will be saved to Excel.
- The MDM will review the speaker add spreadsheet(s), if the speaker additions are appropriate the MDM will add them to the speaker bureau with a "Nominee" classification. (cannot speak at MEPs yet)

4. **Speaker Qualification Process:** - (see attachment for details)

Nominee Classification:

- After a "Nominee" is added to the Speaker Bureau by the MDM, Cogenix will send the Sales Specialist a speaker pre-qualification packet that includes a Speaker Agreement, Promotional Slide Kit and Actiq Risk Management Program forms. (if applicable)
- The Sales Specialist will work with their MDM to set up a face to face meeting or conference call with the potential speaker to review the pre-qualification packet.
- If the speaker is deemed "qualified" by the MDM and signs the "Speaker Agreement" form, then the MDM updates the speaker's classification to "Qualified" and the speaker is eligible to speak at MEPs.

Qualified Classification:

- To become an Approved classification speaker, a Qualified speaker must attend a National Speaker Training meeting or Regional Speaker Development workshop.
- After attending Speaker Training, AM or MDM must evaluate the speaker at an MEP and fill out the "Speaker Evaluation / Profile" form.
- MDM accesses the Qualified speaker's evaluation and if they deem appropriate then the speaker will be elevated to an "Approved" classification.

There are a lot of changes outlined within so please review the attachments for more detailed information. If you have questions please let me know or discuss with your Regional Director, Area Manager or Market Development Manager.

Speaker Identification and Development

Nominee Classification:

- a. The "Nominee" list is generated by the AM and sent monthly to the MDM
 - i. Limitations should be set regarding the number of "Nominees" a region can request on a quarterly basis
 - ii. Limitations should be set by regional needs and legal considerations
 - iii. Exceptions will be allowed on an emergent situation
- b. Nominee criteria
 - i. Must be Sales Specialist targeted Physician
 - ii. Must have significant product clinical experience
 - iii. AM must meet with all potential speakers prior to submission to validate speaker's interest level, commitment to additional clinical training, and speaking experience.
 - iv. The MDM enters the speaker "Nominees" in the Cogenix database
 - v. Cogenix sends a speaker agreement, promotional slide kit, and RMP agreement (Actiq only) directly to the respective Sales Specialist
 - vi. Cogenix notifies the Sales Specialist (cc to MDM) via email that the packet has been sent with FedEx tracking number
 - vii. Sales Specialist coordinates with the MDM to schedule a meeting/phone meeting with the Nominee speaker (Sales Specialist attendance is not mandatory)
- c. MDM conducts a meeting to go over Promotional Slide Kit, speaker guidelines, the Speaker Agreement (exhibit B) expectations, and the RMP (Actiq only)
- d. Cogenix notifies the MDM via email when the signed speaker agreement has been returned

Qualified Speakers:

- a. After MDM goes over the Promotional Slide Kit, speaker guidelines and expectations, and the RMP (Actiq only) and the Speaker Agreement is received by Cogenix the MDM changes speaker Nominee status to "Qualified" in the Cogenix system
- b. The qualified speaker is allowed to speak on behalf of Cephalon.
- c. The Qualified speaker does not have access to the Cephalonspeaker.com website
- d. In order to be elevated to an Approved status Qualified speakers must attend formal speaker training (with few exceptions)

Approved Speakers:

- a. Upon completion of formal speaker training, the MDM or AM is required to complete an evaluation at a MEP before speaker is elevated to Approved status. If after evaluation, speaker is not deemed eligible for status change, speaker remains "Qualified"

- i. The AM sends the evaluation form to the MDM for approval and discusses with MDM upon receipt.
 - ii. The MDM may require additional MEP's or speaker education prior to approval.
- b. After a successful evaluation the MDM reclassifies the speaker in the Cogenix system as "Approved" and checks a box that a formal evaluation has been completed.
- c. Cogenix generates a slide kit agreement for the "Approved" speaker upon receipt
- d. The Slide Kit Agreement is sent via Fed-x to the Speaker with an email to the MDM.
- e. Once the signed slide kit agreement is received, Cogenix sends the Approved speaker a user name, password and Cephalon Speaker Welcome letter and notifies the MDM via email.
- f. MDM insures that the speaker can access the Cephalonspeaker.com website

Speaker Maintenance

Nominee Classification:

- a. A Nominee speaker can maintain this status for no more than 3 months
- b. A Nominee cannot speak until being qualified by an MDM
- c. The MDM will review the "Nominee exception report" on a quarterly basis and make recommendations for deletes to the home office.

Qualified Speakers:

- a. A new speaker must speak within 2 months of being added to the speaker faculty
- b. The Qualified speaker must speak a minimum of two times per 12 month period
- c. The MDM will review the "Qualified exception report" on a quarterly basis and after reviewing with their Sales Director make recommendations for deletes to the home office. This exception report will include both criteria listed above (a and b)

Approved Speakers:

- a. The MDM will meet with (or have a discussion) with all Approved speakers one time per year to review the promotional and clinical slides and discuss Cephalon's speaker guidelines and expectations
- b. Approved speakers must speak a minimum of four times per year
- c. The MDM will review the "Approved exception report" on a quarterly basis and after reviewing with their Sales Director make recommendations for deletes to the home office.

2004 Cephalon Speaker Classifications

Redacted

Actiq	
Approved	<p>A healthcare provider can become "Approved" by attending a speaker training program, speaker development workshop or at the discretion of the Product Director or VP of Marketing. In addition, the approved speaker has received, reviewed and completed all paperwork related to the Actiq Risk Management Program.</p> <p>An approved speaker has access to the promotional slide kit and the CephalonSpeaker.com web site which entitles them to receive slide kits that include the broadest discussion of the product for purposes of scientific exchange</p> <p>To maintain Approved status a speaker must give ≥ 4 presentations within a 12 month time period. Territory Sales Specialist should first look to utilize approved speakers for MEP programs.</p>
Qualified	<p>A healthcare provider becomes "qualified" after extensive discussions with the MDM. During speaker discussions the MDM will review the Promotional Slide Kit, review Cephalon's Speaker expectations, insure signature of the Speaker Agreement form, completes a product specific Speaker Profile sheet and reviews and completes all paperwork related to the Actiq Risk Management Program.</p> <p>Qualified speakers have access to the Promotional slide kits but <u>do not</u> have access to the Cephalonspeaker.com web site.</p> <p>To maintain Qualified status a speaker must give their first talk within 2 months of joining the faculty and must give ≥ 2 presentations within a 12 month time period. Qualified speakers should be utilized by Territory Sales Specialist if no appropriate approved speakers are available.</p>

2004 Cephalon Speaker Classifications - continued

Redacted

	Actiq
Nominee	<p>A Nominee speaker <u>cannot</u> speak until they are qualified by an MDM.</p> <p>On a quarterly basis potential speakers are identified by Territory Sales Specialists/Area Managers and are forwarded to the MDM. The MDM consolidates, reviews with the Regional Director and adds potential speakers as "Nominees" to the speaker database. The potential speaker will remain a "Nominee" until the MDM completes their qualification process (as defined in the Qualified section)</p> <p>Nominees <u>do not</u> have access to the promotional slide kits or the Cephalonspeaker.com web site. A Nominee will maintain this classification for a maximum of 3 months. During that time they should be elevated in their status or removed from the database. A "Nominee" can only be viewed by the MDM, AM and RSD in the Speaker database.</p>

- MDM will be required to review all Speakers and classifications with Regional Director on a quarterly basis.
- MDM will be required to review all Speakers and Classifications with Marketing on a semi-annual basis.

2004 Cephalon Inc. Speaker Honorarium Schedule

Medical Education Programs (MEP)

Speaker Classification	Maximum Honorarium	Maximum Honorarium additional talk(s)
Approved	\$1,500	\$500/talk
Qualified	\$1,000	\$500/talk

- No Maximum honorarium per day

Teleconferences

Speaker Classification	Maximum Honorarium	Maximum Honorarium additional teleconference(s)
Approved	\$750	\$500
Qualified	\$500	\$300

- No Maximum honorarium per day



SPEAKER EVALUATION / PROFILE FORM
(For Internal Cephalon Use Only)

Purpose: To assist the Market Development Manager and/or Area Manager with Speaker Development by identifying speaker candidate's strengths and developmental opportunities.

Physician Name:

Address:

Address:

City:

State:

ZIP:

Office Phone:

Cell Phone:

Fax:

Email Address:

Other:

Office Contact:

Primary Specialty:

Secondary Specialty:

Primary Area of Expertise:

Speaker Classification (Current): Check where applicable

<i>Brand</i>	<i>Approved</i>	<i>Qualified</i>	<i>Nominee</i>
Redacted			
ACTIQ®	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Speaker for Other Companies: Yes No

Companies Currently Speaking For:

SPEAKER EVALUATION / PROFILE FORM

(For Internal Cephalon Use Only)

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Rate 1 - 5 in the Following Areas: Check one per category

National Influence

- 5** This person is always requested for national meetings – speaks all the time at major medical symposia on specific areas of expertise
- 4** This person is often requested for national meetings – speaks sometimes / sporadically at medical symposia on specific areas of expertise
- 3** This person is an up and comer at a major medical center and is establishing him/herself as an expert on a particular topic
- 2** This person does studies, but does not carry the weight or credibility needed to move opinion
- 1** I would not recommend this person for a national symposium at this time

Regional Influence

- 5** This person exerts major influence at a regional level and is willing to do the more regionally based engagements
- 4** This person exerts major influence at a regional level. Has the ability to become a national speaker
- 3** This person is an up and comer and with training, can be a strong regional influencer
- 2** This person has local influence, but does not carry the weight or credibility needed to move opinion at a higher level
- 1** I would not recommend this person for a regional symposium at this time

Local Influence (Good MEP Doc)

- 5** Strong understanding of the product, delivers key messages with authority, well respected by field and able to influence docs in audience
- 4** Good understanding, clinical experience with product, not the best speaker, but adequate
- 3** Moderate understanding / clinical experience with product – could be developed with more training
- 2** Wants to speak more – but needs better training and understanding of product
- 1** Weak – recommend we discontinue using as MEP doc

Speaking Ability

- 5** Excellent
- 4** Good
- 3** Average
- 2** Weak
- 1** Extremely Poor

SPEAKER EVALUATION / PROFILE FORM
 (For Internal Cephalon Use Only)
 Page 3

Knowledge of Data and Studies with Product(s)

- 5** Knows all the studies extremely well, even those outside of area of expertise very strong on product basics (not many will be at this rating)
- 4** Knows product basics, some of the sleep studies, but is well versed on studies within core area of expertise
- 3** Knows core data within area of expertise well and some product basics, but clearly needs stronger training on product basics
- 2** OK on product basics, OK on knowledge of studies
- 1** Weak on product basics, weak on study data

Clinical Experience with Product(s)

- 5** Has adopted product(s) in the practice. Uses the product in a wide variety of disease states for similar conditions
- 4** Uses a substantial amount of product(s) – specifically for one or two disease states
- 3** Moderate writer, uses product(s) for a very specific patient type
- 2** Dabbler with product(s) – has opportunity to use more if better informed
- 1** Doesn't write – either academic or non-clinical setting

Proposed Venue(s) for speakers presentations: Check where applicable

MEP (Dinner)	Roundtable (Small Group)	CME (Grand Rounds)	Teleconference	Consultant Meeting
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Computer Skills Rating: Check where applicable

Excellent	Very Good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Has Speaker Attended a Consultant Meeting? Yes No

Date: Location:

Has Speaker Attended a Speaker Development Workshop? Yes No

Date: Location:



SALES BULLETIN

#15

DATE: May 5, 2004
TO: Sales/Marketing Personnel
CC: Edward Berg, Rod Hughes, Kiumars Vadiei
FROM: Lynne Brookes and Roy Craig
RE: New Process for Educational Grants

As of May 10, 2004, all Educational Grants will be reviewed and approved by the newly appointed Cephalon Educational Grant Committee. This Committee will consist of Representative members of the Medical Affairs, Scientific Communications, and Legal Departments; and will meet with bi-weekly or monthly, as needed, to evaluate the grant request submitted.

As a reminder, Cephalon makes Educational Grants to allow the independent communication and exchange of scientific information. Therefore, Cephalon cannot control the content, the speakers, or any aspect of the attendant discussion. Further, the subject matter likely to be discussed must not be unduly narrow so as to primarily focus on any particular Cephalon Policy, grants must not be made to individual physicians or to physician groups. Finally, grants can never be made to reward or induce the prescribing of a Cephalon drug.

All field grant requests should be submitted on the Educational Grant Draft Request form provided herein attached or located on the Cephalon Intranet under the Sales & Marketing tab, approximately one month in advance of the needed signature

along with any and all correspondence regarding the grant (such as a written grant request or an email discussing the grant request, whether internal or external). Internal (West Chester - based) grants should be presented by the appropriate Cephalon employee supporting the grant funding request (with all appropriated documentation and correspondence also provided.)

Additionally, and after Educational Grant Committee Approval, all grants must be made either through the Cephalon Medical Education Agreement, or through an Agreement provided by the requestor and reviewed and approved by the Committee. No promises of grant funding may be made until approval by the Committee. Because Cephalon supports independent educational grants based primarily on the perceived scientific need for full objective discussion around the medical topics of interest to our company, the Committee will sometimes either support the grant only with a change in topic focus or may even deny the grant.

The Grant Committee will meet every two weeks from October through May, and Monthly through the summer and early fall, so grants must be submitted in a timely manner (one month prior to the needed determination) to allow for review and possible comment.

All questions regarding this new process should be directed to your Sales or Products Directors.

EDUCATIONAL GRANT GUIDELINES

- A. All educational grants must be for a legitimate medical educational purpose and must not be for discussion of any particular product.
- B. All educational grant recipients must be independently responsible for developing content.
- C. All educational grant recipients must be ultimately responsible for speaker selection.
- D. Educational grants should only be made with a Medical Education Agreement setting forth the above and other relevant terms signed by a representative of the institution requesting the grant and the Cephalon representative.
- E. The standard Cephalon Medical Education Agreement may be used or a medical education agreement supplied by the institution as long as the agreement contains all the relevant terms covered by the Cephalon medical education agreement.
- F. When the standard Cephalon Medical Education Agreement is used rather than one supplied by the institution, Form-1 should be used if the program potentially involves content related to areas of medicine in which Provigil or Gabitril may be considered. Form-2 is to be used when providing a grant for a program that potentially involves content related to areas of medicine in which Actiq may be considered.
- G. Appropriate documentation of request is required.
- H. If the above conditions are met, the grant agreement, up to \$1,500.00 may be signed by the Area Manager and Regional Director. If the grant agreement is for more than \$1,500.00, the grant must also be approved by the Vice President, Sales. After the appropriate paper work has been submitted and signed, the Educational Grant Committee will review for approval.

INSTRUCTIONS

REP/NAM/MDM: Complete all shaded areas. Fax form with backup documentation to Area Manager / Regional Director *at least one month prior to date draft needed.*

AM: Review, sign and fax form with all backup documentation to Regional Director.

Regional Director: Review, sign and fax to Draft Request Coordinator (610-738-6371) for submission to Grant Committee.

Draft Request Coordinator: Will notify AM and RD of approval and will log in to Draft Request Budget.



EDUCATIONAL GRANT DRAFT REQUEST

TODAY'S DATE: _____ DRAFT #: _____ AMOUNT: _____
(To be assigned by AM/ Director)

INSTITUTION NAME: _____

STREET ADDRESS: _____

CITY: _____ STATE: _____ ZIP: _____

TAX ID#: _____

PRODUCT: (CHECK ONE) Redacted ACTIQ

PROGRAM TITLE: _____ PROGRAM DATE: _____

IS CEPHALON ONLY SPONSOR OF PROGRAM: Y N

TYPE OF PROGRAM: _____
(Symposia, Teleconference, Grand rounds, etc)

WILL GRANT SUPPORT ENDURING MATERIALS: Y N

DESCRIBE ANY CEPHALON INVOLVEMENT IN THE GRANT REQUEST TO DATE: _____

DESCRIBE ANY FUTURE CEPHALON INVOLVEMENT CONTEMPLATED: _____

REQUESTOR: _____ TERRITORY #: _____

MANAGER /DIRECTOR SIGNATURE: _____

PRINT NAME: _____

REGIONAL DIRECTOR SIGNATURE: _____

PRINT NAME: _____

IF GREATER THAN \$1500 OR IF REQUIRED BY CEPHALON STANDARDS FOR DRAFT REQUESTS:

VICE PRESIDENT OF SALES SIGNATURE: _____

PRINT NAME: _____



FORM-1: MEDICAL EDUCATION AGREEMENT

As a condition of Cephalon, Inc's contribution of funds to support an independent medical education program (with or without CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of _____, _____ by and between Cephalon, Inc. ("Cephalon") and _____ ("Provider") regarding a medical education program sponsored by Cephalon entitled "_____" to be held on _____, _____. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.



9. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

10. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

11. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

[NAME OF PROVIDER]

CEPHALON, INC.

By: _____
Name: _____
Title: _____

By: _____
Name: _____
Title _____



FORM-2: MEDICAL EDUCATION AGREEMENT

As a condition of Cephalon, Inc's contribution of funds to support an independent medical education program (with or without CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of _____, _____ by and between Cephalon, Inc. ("Cephalon") and _____ ("Provider") regarding a medical education program sponsored by Cephalon entitled "_____" to be held on _____, _____. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.



8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. ACTIQ Risk Management Program. Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.*
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.



IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

[NAME OF PROVIDER]

CEPHALON, INC.

By: _____
Name: _____
Title: _____

By: _____
Name: _____
Title: _____



SPEAKER EVALUATION / PROFILE FORM
(For Internal Cephalon Use Only)
Page 4

Has Speaker Attended a Speaker Training Meeting?

Yes No

Date:

Location:

Areas for Development:

Performance in Previous MEPs:

Additional Comments / Notes:

Sales Representative:	
Area Manager:	
Market Development Manager:	

Redacted

From: Hoopes, Jane
Sent: Thursday, February 26, 2004 2:29 PM
To: US Sales
Cc: Craig, Roy; Sales Operations; 626 (Sales Training); Brookes, Lynne; Fatholahi, Shawn; Patel, Pranay P; Bannach, Roxana; Kovaleski, Kevin; Berg, Edward; Kirsch, Paul
Subject: Sales Bulletin #13 - **Redacted** Flashcard (PRO 293)
*Sent on behalf of **Redacted** marketing Team*

Please see the important attached bulletin.

Jane Hoopes
Field Sales Administration Analyst
610-738-6528
610-738-6371 fax
jhoopes@cephalon.com

file://I:\SALES\Roy\Sales%20Bulletin\Bulletin%2013%20PRO%20293\Sales%20Bulletin... 2/27/2004

Confidential Treatment Requested by Cephalon, Inc.
CONFIDENTIAL PER STIPULATION AND PROTECTIVE ORDER

Confidential

CEPH-CT-GEN-00006730
CEP_TPP_CTAG10751063
TEVA_MDL_A_05445673

P-11460 _ 00030

Redacted

Confidential Treatment Requested by Cephalon, Inc.
CONFIDENTIAL PER STIPULATION AND PROTECTIVE ORDER

Confidential

CEPH-CT-GEN-00006731
CEP_TPP_CTAG10751064
TEVA_MDL_A_05445674

P-11460 _ 00031

Redacted

2/27/2004

2

SAL-BUL-04-012

From: Hoopes, Jane
Sent: Monday, February 23, 2004 11:01 AM
To: US Sales
Cc: Sales Operations; 626 (Sales Training); Brookes, Lynne; Fatholahi, Shawn; Patel, Pranay P; Bannach, Roxana; Kovaleski, Kevin; Berg, Edward; Kirsch, Paul; Craig, Roy
Subject: Sales Bulletin 12 - Interim Use of Redacted Promotional Materials
Sent on behalf of the Redacted Marketing Team

Please see the attached Sales Bulletin regarding the Interim Use of Redacted Promotional Materials.

Jane Hoopes
Field Sales Administration Analyst
610-738-6528
610-738-6371 fax
jhoopes@cephalon.com

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Confidential Treatment Requested by Cephalon, Inc.
CONFIDENTIAL PER STIPULATION AND PROTECTIVE ORDER

Confidential

CEPH-CT-GEN-00006733
CEP_TPP_CTAG10751066
TEVA_MDL_A_05445676

P-11460 _ 00033



SALES BULLETIN

#11

DATE: February 12, 2004

TO: U.S. Sales, Marketing, Sales
Training, Sales Operations

CC: Ed Berg, Randy Zakreski

FROM: Roy Craig

RE: **CEPHALON GUIDELINES FOR PROMOTIONAL
MEPS (MEDICAL EDUCATION PROGRAMS)**

- Cephalon considers these programs to be primarily promotional in nature. The purpose of the primary part of the presentation is to provide on-label information to attendees.
- The program should be clearly identified as a Company - (i.e., Cephalon) sponsored program (as opposed to an Independent Program).
- Presentations must begin with a substantive discussion of the products labeled uses presented in a balanced and objective manner. This part of the presentation may also include discussion of product attributes not necessarily related to the products specific indication (i.e., mechanism of action, pre-clinical studies involving the product etc., but not off-label uses of the product).
- After a substantive discussion of the products labeled use has taken place, the speaker may discuss how they use the product in their own

2/12/04

SAL-BUL-04-011

practice followed by a question and answer period.

- During the question and answer period presenters are free to provide any and all scientific information that they find relevant, including off-label information on Cephalon products, but should make clear when the information is off-label.
- Discussions of any other therapeutic options must also be well balanced, accurate, and objective.
- Cephalon representatives may not recommend or suggest that the speaker address any off-label use of any product.

From: Hoopes, Jane
Sent: Thursday, February 12, 2004 1:56 PM
To: US Sales; 626 (Sales Training); Sales Operations; 631 (Marketing)
Cc: Berg, Edward; Zakreski, Randy
Subject: SALES BULLETIN #11 - CEPHALON GUIDELINES FOR PROMOTIONAL MEPS (MEDICAL EDUCATION PROGRAMS)
Sent on behalf of Roy Craig.

In 2004, MEP programs will once again be a critical tool for success in every territory. I've been very impressed with how many MEP programs have been booked already and I'm certain that those of you who have been most aggressive in this area are starting 2004 with a big advantage.

While we strongly encourage the aggressive use of these very effective programs, it is critically important that every person in the Cephalon sales force understands the guidelines that we and our MEP speakers must follow regarding these programs. I have attached a document that summarizes the most essential of these guidelines. Please carefully review this document to make sure that you understand each point. If you have any questions or uncertainty about your obligations or the obligations of a Cephalon MEP speaker, please contact your manager.

Jane Hoopes
Field Sales Administration Analyst
610-738-6528
610-738-6371 fax
jhoopes@cephalon.com



SALES BULLETIN

#10

DATE: January 28, 2004

TO: U.S. Sales

CC: Marketing, Sales Training,
Global Product Safety (Richard Civil,
Robert Bader, Helen Wentz, Kay
McGhee), Legal

FROM: Kiumars Q Vadie

**RE: REPORTING OF ADVERSE EVENTS AND
PRODUCT COMPLAINTS**

This is a very important message regarding the procedure for handling adverse drug experience (ADE) and product complaint (PC) reports associated with a Cephalon marketed product.

In order to ensure that Cephalon meets all applicable Federal regulations, it is imperative that all Cephalon employees follow the procedures outlined in SOP-0256-D8 upon receipt of any product-related ADE or complaint of a medical or technical nature. Accordingly, any information received regarding a PC or a possible ADE associated with

1/28/04

SAL-BUL-04-010

a Cephalon marketed product must be transcribed on the ADE/PC worksheet and immediately forwarded via email, fax or hand-delivery to Professional Services at the following address:

Cephalon, Inc.
Medical Affairs Department
Professional Services
145 Brandywine Parkway
West Chester, PA 19380-4245
email: USMedInfo@Cephalon.com
fax: (610) 738-6669
telephone: 1-(800) 896-5855

Product complaint and ADE reports can be received from any source, including phone calls, letters, personal communications, e-mail, fax, publications or on the Internet. If you receive such a report, do not attempt to explain or provide information concerning the event to the reporter. Rather, obtain as much relevant information as possible (see ADE/Product Complaint Form) and inform the reporter that someone from the company will contact him/her for follow-up.

If you forward the report electronically (ie, email or fax), you must also mail the original report to the address above.

The SOP referenced above can be located on the Cephalon intranet. If you have any questions about complaints or this procedure, please give me a call at ext 86325.

Kiumars Q Vadieli, Ph.D., R.Ph.
Sr. Director, Professional Services/ Medical Information

From: Hoopes, Jane
Sent: Wednesday, January 28, 2004 2:20 PM
To: US Sales
Cc: 631 (Marketing); 626 (Sales Training); Civil, Richard; Bader, Robert; Wentz, Helen; McGhee, Kay; Berg, Edward; Craig, Roy; Vadieli, Kiumars; 628 (Sales Operations)
Subject: Sales Bulletin #10 - Reporting of Adverse Events and Product Complaints
Please see the attached Sales Bulletin regarding the Reporting of Adverse Events and Product Complaints.

Jane Hoopes

Field Sales Administration Analyst

610-738-6528

610-738-6371 fax

jhoopes@cephalon.com

file://I:\SALES\Roy\Sales%20Bulletin\Bulletin%2010%20Adverse%20Events-Prod%20C... 1/28/2004

Confidential Treatment Requested by Cephalon, Inc.
CONFIDENTIAL PER STIPULATION AND PROTECTIVE ORDER

Confidential

CEPH-CT-GEN-00006739
CEP_TPP_CTAG10751072
TEVA_MDL_A_05445682

P-11460 _ 00039



SALES BULLETIN

#9

DATE: December 12, 2003

TO: U.S. Sales

CC: Ed Berg
Randy Zakreski
Paula Castagno
Andy Pyfer
Lynne Brookes

FROM: Roy Craig

RE: **Ensuring Appropriate Targeting And
Promotion of ACTIQ**

Cephalon Territory Sales Specialists (TSS) should only promote Actiq to pain specialists skilled in the use of opioids. Any physician who averages 4 or more opioid prescriptions per month may be initially considered to be skilled in the use of opioids. The physicians' opioid prescribing volume may be determined by third party prescription data purchased by Cephalon or by independent verification of the physicians prescribing activity on the part of the TSS.

If a TSS has information that a physician has prescribed Actiq but has not met the threshold of opioid prescribing volume described above, the TSS may call on the physician in the interest ensuring safe use of Actiq.

12/12/03

SAL-BUL-03-009

The following activities should be performed in the field to ensure appropriate targeting and promotion of ACTIQ.

- **Physician Skilled in the Use of Opioids**
 - Sales specialists must confirm targeted physicians are aware of the risks/benefits associated with prescribing opioids. The risks of prescribing opioids range from typical opioid side effects such as nausea, vomiting, dizziness and sedation to more serious adverse events such as respiratory depression. These risks, as well as others including abuse, addiction and diversion must be conveyed to all prescribers.

- **Dissemination of Pain Treatment Guidelines**
 - Sales specialists will be provided pain treatment guidelines published by the American Pain Society. These treatment guidelines will be disseminated by sales specialists at their discretion to further educate physicians regarding the risks, benefits and appropriate use of opioids in the management of pain.

- **Awareness of Medical Education Initiatives**
 - Sales specialists will be made aware of medical education initiatives implemented or supported by Cephalon regarding opioid use, abuse, addiction or diversion. Sales specialists will have the opportunity to make these initiatives/programs available to physicians interested in participating and furthering their knowledge of the risks, benefits and appropriate use of opioids in the management of pain.

12/12/2003

2

SAL-BUL-03-009

From: Hoopes, Jane
Sent: Friday, December 12, 2003 11:30 AM
To: US Sales
Cc: Berg, Edward; Zakreski, Randy; Pyfer, Andy; Castagno, Paula; Brookes, Lynne
Subject: Sales Bulletin #9 - Ensuring Appropriate Targeting And Promotion of ACTIQ
Sent on behalf of Roy Craig

As we complete the process of combining and expanding the Cephalon sales force, we will be making calls on many more physicians.

The attached document provides important information on which physicians may be targeted for Actiq promotion. Please read this document carefully and, effective immediately, ensure that you are adhering to these guidelines.

Jane Hoopes
610-738-6528
jhoopes@cephalon.com

file:///I:\SALES\Roy\Sales%20Bulletin\Bulletin%209%20Targ-Promo%20Actiq\Email%... 12/12/2003

Confidential Treatment Requested by Cephalon, Inc.
CONFIDENTIAL PER STIPULATION AND PROTECTIVE ORDER

Confidential

CEPH-CT-GEN-00006742
CEP_TPP_CTAG10751075
TEVA_MDL_A_05445685

P-11460 _ 00042



SALES BULLETIN

#8

DATE: November 4, 2003

TO: U.S. Sales

CC: Ed Berg
Sales Operations
Sales Training
Marketing

FROM: Roy Craig

RE: CEPHALON DRAFT
REQUEST STANDARDS
FOR CORPORATE
CONTRIBUTIONS,
EDUCATIONAL GRANTS,
PRECEPTORSHIPS,
TUTORIALS AND DISPLAYS

1. Corporate Contributions

8/18/2003

SAL-BUL-03-007

- A. Does the recipient purchase, prescribe or influence formulary status for any Cephalon Product? (If yes, contribution must be approved by Vice President, Sales and by Cephalon legal department))
- B. Is the recipient a 501 (c)(3) charity or a well-recognized national, regional or local medical society? (e.g. AAPM, ASCO, ALS Foundation, etc.) (If no, contribution must be approved by Vice President, Sales.)
- C. Is any physician or formulary decision maker going to directly benefit from this contribution at Cephalon's direction? (E.g. a contribution for a charity golf tournament where Cephalon chooses the physician(s) who play.) (If yes, contribution must be approved by Vice President, Sales.)
- D. Appropriate documentation of request is required
- E. Is the contribution over \$1,500.00? (If yes, contribution must be approved by Vice President, Sales.)

2. Educational Grants

- A. All educational grants must be for a legitimate medical educational purpose and must not be for discussion of any particular product.
- B. All educational grant recipients must be independently responsible for developing content.
- C. All educational grant recipients must be ultimately responsible for speaker selection.
- D. Educational grants should only be made with a medical education grant agreement setting forth the above and other relevant terms signed by a representative of the institution requesting the grant and the Cephalon representative.

11/4/2003

2

SAL-BUL-03-005

- E. The standard Cephalon medical education grant agreement may be used or a medical education grant agreement supplied by the institution as long as the agreement contains all the relevant terms covered by the Cephalon medical education agreement.
- F. When the standard Cephalon medical education agreement is used rather than one supplied by the institution, **Form-1** should be used if the program potentially involves content related to areas of medicine in which Provigil or Gabitril may be considered. **Form-2** is to be used when providing a grant for a program that potentially involves content related to areas of medicine in which Actiq may be considered.
- G. Appropriate documentation of request is required
- H. If all of these conditions are met, the grant agreement, up to \$1,500.00 may be signed by the Area Manager and Regional Director. If the grant agreement is for more than \$1,500.00, the grant must be approved by the Vice President, Sales

3. Preceptorships

- A. Preceptorships with healthcare providers must be for the education/training of the Cephalon representative.
- B. A fee for this service may be paid to the healthcare professional, not to exceed \$500
- C. Preceptorships may not be used as a detailing opportunity or as an opportunity to reward high prescribers
- D. Excessive use of this training tool is inappropriate.
- E. Appropriate documentation of request is required

4. Tutorials

11/4/2003

3

SAL-BUL-03-005

- A. Tutorials with healthcare providers must be for the education/training of the Cephalon representative.
- B. A fee for this service may be paid to the healthcare professional, not to exceed \$500
- C. Tutorials may not be used as a detailing opportunity, as an opportunity to reward high prescribers or as a way for the physician to be required to read or present any certain articles.
- D. Excessive use of this training tool is inappropriate.
- E. Appropriate documentation of request is required

5. Display Fees

- A. Display fees are fees paid to institutions, medical societies etc. to display and promote Cephalon products at a specific time and place.
- B. All promotional material must be approved by the promotional review committee
- C. Appropriate documentation of request is required

11/4/2003

4

SAL-BUL-03-005

FORM-1: MEDICAL EDUCATION AGREEMENT

As a condition of Cephalon, Inc's contribution of funds to support an independent medical education program (with or without CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

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1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

C:\Documents and Settings\Jhoopes\Local Settings\Temporary Internet Files\OLK2B\Form-1 MedEd Agreement (Provigil-Gabitril)1.doc

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

10. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

11. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

[NAME OF PROVIDER]

CEPHALON, INC.

By: _____
Name: _____
Title: _____

By: _____
Name: _____
Title _____

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FORM-2: MEDICAL EDUCATION AGREEMENT

As a condition of Cephalon, Inc's contribution of funds to support an independent medical education program (with or without CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of _____, _____ by and between Cephalon, Inc. ("Cephalon") and _____ ("Provider") regarding a medical education program sponsored by Cephalon entitled "_____" to be held on _____, _____. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

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7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. ACTIQ Risk Management Program. Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.*
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

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(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

[NAME OF PROVIDER]

CEPHALON, INC.

By: _____
Name: _____
Title: _____

By: _____
Name: _____
Title: _____

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CEPH-CT-GEN-00006751
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TEVA_MDL_A_05445694

P-11460 _ 00051



SALES BULLETIN

#7

DATE: February 18, 2004

TO: Alan Beckman, Chuck
DeWildt, Ryan Barnes, Mike
Wetherholt, Mike Thiem,
Bill Cunningham

CC: Ed Berg
John Osborn
Carl Savini
Bob Roche
Greg Martin
Dan Scott

FROM: Roy Craig

RE: REGIONAL DIRECTOR FCR
COMPLIANCE REVIEW

1- Regional Directors are required to review all field contact reports (FCRs) written by the area managers reporting to them in a timely manner. This may be done before or after the FCR

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has been sent to the representative on whom the FCR was written.

- 2- The purpose of this review will help to ensure that sales representatives and area managers are engaging in acceptable sales and management practices including, but not limited to, following all applicable Cephalon compliance policies.
- 3- If, upon a reviewing an FCR, the Regional Director (RD) determines that the area manager did not and had no need to address a potential or actual compliance violation within the report no further action is required.
- 4- If, upon a reviewing an FCR, the RD determines that the area manager did address a potential or actual compliance violation on the part of the sales representative and did so adequately, a copy of the FCR should be sent to the Vice President, Sales.
- 5- If, upon a reviewing an FCR, the RD determines that there was a potential or actual compliance violation on the part of sales representative that was not adequately addressed by the area manager, the RD will ensure that adequate measures are taken to address the matter and a copy of the FCR along with a description of the measures taken should be sent to the Vice President, Sales.
- 6- If, upon a reviewing an FCR, the RD determines that there was a potential or actual compliance violation on the part of area manager, the RD will ensure that adequate measures are taken to address the matter and a copy of the FCR along with a description of the measures taken should be sent to the Vice President, Sales.
- 7- The RD should contact the Vice President, Sales, Cephalon legal support or Human Resource support as needed if assistance is required to determine if a potential or actual compliance violation has occurred and/or to determine appropriate measures that need to be taken.

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SAL-BUL-03-005



SALES BULLETIN #6

DATE: February 18, 2004
TO: Cephalon Sales Organization
FROM: Kiumars Q. Vadie / Dana Luscombe
RE: E-MIRF System Goes Live!!!

Electronic MIRF Requests

In a collaborative effort between Professional Services and Sales Operations, a significant enhancement has been made to the way you will process requests for medical information. This is the first step in providing faster processing and greater customer service.

The "EMIRF" process allows you to submit "Medical Information Request Forms" electronically using your SMART or PRISM system.

Advantages of the EMIRF process!!!!

- ▶ You no longer need to manually fill out the paper MIRF form.
- ▶ You no longer have to mail or fax the MIRF form(s) to Medical Affairs.
- ▶ The Physician's signature is no longer required on the MIRF form
- ▶ Automated, electronic submission to Medical Affairs which will speed up MIRF processing
- ▶ Simply replicate Lotus Notes and EMIRF requests will be sent to Medical Affairs each morning

How do I utilize the New EMIRF functionality??

The EMIRF functionality has been embedded into your SMART and PRISM systems and will be available the next time you replicate Lotus Notes.


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A MIRF request can be submitted two (2) ways:


1. In conjunction with a Physician "Call"

- ▶ Click "New Call" from the Physician Profile or Physician List Screen.
- ▶ From the "Call Activity" form click on the "MIRF Request" button

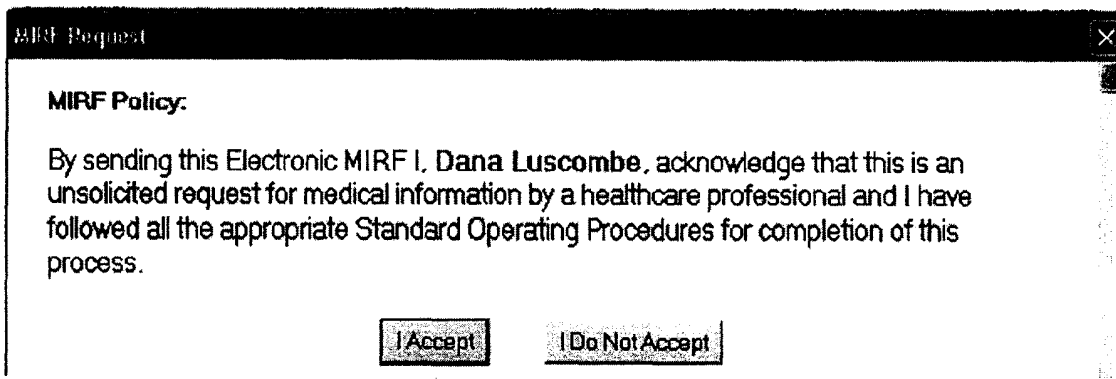
 which will display the Cephalon "Legal Disclaimer".

2. As a separate MIRF request

- ▶ Double click on the Physician Profile that requested the Medical Information
- ▶ From the "Physician Profile" screen click on the "MIRF Request" button

 which will display the Cephalon "Legal Disclaimer".

Cephalon "MIRF Policy" Screen.



MIRF Policy:

By sending this Electronic MIRF I, Dana Luscombe, acknowledge that this is an unsolicited request for medical information by a healthcare professional and I have followed all the appropriate Standard Operating Procedures for completion of this process.

- ▶ Before you can proceed, you are required to acknowledge that the MIRF request is unsolicited and that you have followed all Standard Operating procedures.
 - *Your "acceptance" indicates that the request was unsolicited*

After acceptance of the MIRF Policy statement the "MIRF Request" form will display.

Cephalon MIRF Request [X]

Make any necessary address changes below, select product and enter question:

Territory:	7220106
Lab Name:	Smith
First Name:	Sarstrom
Docid:	MD
Address 1:	3601 S. 4th Trfwy
Address 2:	
City:	Leavenworth
State:	KS
Zip:	66048
Fax:	
Email:	

Received Request Via: Visit Phone Email Fax MEP Convention

Deliver MIRF Via: Mail

Product: Redacted Actiq

Question: (r500 Characters) _____

Filling out and Sending the "MIRF Request" form:

- ▶ The address fields in white are editable; you can enter a custom address if applicable.
 - Make sure the address is correct, if not cancel the request and correct the address in your SMART/PRISM profile
- ▶ Fill out all required fields -
 - Address, Received Request Via, Product, Question, Salutation
- ▶ When the MIRF Request is complete, click on "Send MIRF".
- ▶ Replicate Lotus Notes to send the MIRF Request to Medical Affairs.


Viewing Physician MIRF History:

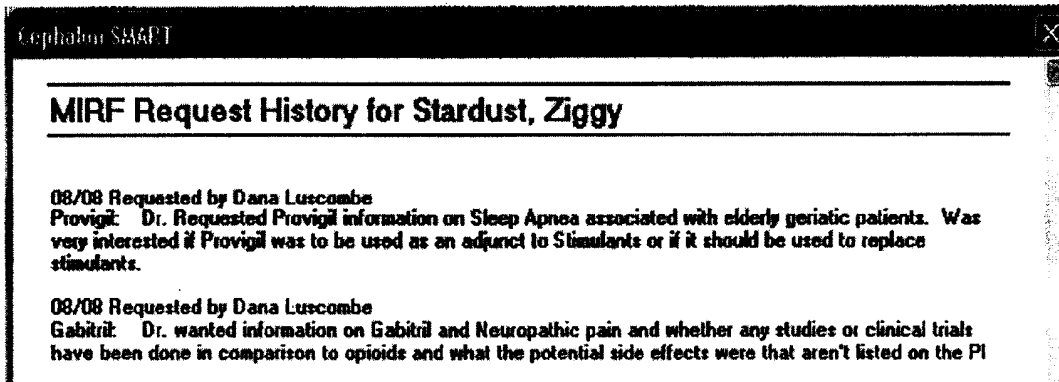
1. After sending a MIRF Request, the MIRF information will be stored with the physician

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2. Click on the “MIRF History” button  from the Physician profile to view historical MIRF requests.



That's it, an easy to use tool that will allow you to request and expedite Medical Information at a physician level.

Reminder:

You may inquire as to whether the physician received or was satisfied with the MIRF response, but you may not make claims about off-label information

If you have MIRF or business questions please contact Kiumars Q. Vadie, if you have SMART or PRISM questions please contact Dana Luscombe.

Kiumars Q. Vadie, Ph.D., R.Ph.
Director, Professional Services/Medical Information
Medical Affairs Department
610.738.6325 phone
610.738.6669 fax

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CEPH-CT-GEN-00006760
CEP_TPP_CTAG10751093

TEVA_MDL_A_05445703

P-11460 _ 00060

SALES BULLETIN

#4

DATE: July 23, 2003
TO: Cephalon Sales Organization
FROM: Roy Craig
RE: CEPHALON TUTORIALS

The recent implementation of HIPAA guidelines has caused some offices to change the policies for physician/sales representative interactions. One of the most common changes has been on the opportunity to conduct preceptorships with key physicians within the community.

Therefore, we are implementing a new program called Cephalon Tutorials. You will continue to be able to participate in preceptorships where they are allowed, or you may use tutorials at the discretion of you and your manager. As with preceptorships, these tutorials will be designed to give you the opportunity to learn more about the physician's practice, prescribing habits, and treatment goals.

The tutorials will normally be conducted over the lunch hour, although they could take place during other times of business operation. The sales representative would schedule a luncheon with the physician and ask that the physician give the sales representative a one hour overview of their specific practice. In some cases, two Cephalon employees may attend a single tutorial. The physician and sales representative could select a specific disease state for the physician

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to review. The physician would then prepare a one hour presentation reviewing the diagnoses criteria, common symptoms and treatment options for both the disease and associated symptoms as well as the physician's specific treatment goals. It is important that the physician present the information from their specific point of view. At the end of the presentation the sales representative would be given the opportunity to ask questions in an effort to clarify any points.

In exchange for this tutorial, Cephalon will provide a fee in the form of a corporate contribution not to exceed \$500, similar to the expected fee provided for a preceptorship.

This program represents an excellent opportunity for "classroom" style learning in a real world environment. The physician benefits from putting together the presentation, researching the diagnostic and therapeutic options, and practicing their presentation skills. The physician is also given the opportunity to get to know the sales representative better and forge a better, more consultative relationship.

Tutorials should not be used for improper purposes. For example, tutorials cannot be used as a detailing opportunity, as an opportunity to reward high prescribers, or as a way for the physician to be required to read or present any certain articles. Similarly, overuse of this training tool is inappropriate. Misuse of this program could result in termination of this program for either individual representatives or in its entirety.

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SAL-BUL-03-004

SALES BULLETIN

#3

DATE: July 23, 2003

TO: CNS and PCS Sales Force

FROM: Kiumars Vadie

RE: SUBMISSION OF MIRFs

CC: Lynne Brookes, Kevin Kovaleski, Roxanna Bannach-Lin, Ray Hage, Matt McKenna, Elizabeth Frand, Andy Pyfer, Christine Wells, Paula Castagno, Ed Berg, Dan Scott, Brian Pomento, Dean Robinson, Lauren Mangus

The purpose of this bulletin communication is to reinforce some of the important issues regarding submissions of MIRFs and provide you with an update regarding this process.

PROCESS

Please continue to follow the steps described below to ensure accurate and prompt processing of the MIRFs you submit to the Professional Services:

1) Include questions only from one product on each MIRF (e.g., Only **Redacted** questions on one MIRF).

2) Questions should be specific and clear.

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Note: General and vague questions such as "use in psychiatric area", "all post APA data", "Dackis Presentation at APA" are not appropriate.

Manuscripts or data that are published or presented in medical meetings, in particular, those that are outside product labeling, are always provided with the accompanying standard response (e.g., Rammohan article: MS Fatigue; Hassmann APA poster: Adjunct therapy in depression). The articles or posters are usually enclosed with the standard response.

Make sure the requestor (e.g., physician) is specific about his/her needs for information.

Providing general and vague questions would significantly delay our response time since we have to call the representative or the MD for clarification.

3) Questions should NOT be pretyped on the MIRF.

4) There should NOT be any reference (e.g., Letter number) to the Standard Response Letters on the MIRFs. These letters are available to you via Intranet for "Educational Purposes Only." You should only state the question(s) that the healthcare professional is asking (For example, Please send all ADHD information [PROV026]).

5) All MIRFs should be signed by physician or a healthcare professional.

6) You should NOT modify MIRF forms. Please use the MIRF form that is currently posted on the Extranet.

7) Make sure the address is correct (we have a fair number of returned mail).

8) The MIRF forms should be used for requests for medical questions and NOT be used for reporting Adverse Events or Product Complaints. You must use the AE/PC Worksheet in these cases.

UPDATE on Submitted MIRFs

Considering the large volume of MIRFs in the recent months, Professional Services has recruited additional support to meet the time line for processing MIRFs. However, we are slightly behind our targeted time line for processing submitted MIRFs. The date for processing MIRFs as of June 24, is as follows:

ACTIQ - All requests completed

Redacted

COMING SOON in July 2003

A new initiative between Professional Services and Sales would allow electronic submission of MIRFs (E-MIRF) in near future. This process would be mutually beneficial and should significantly reduce our response time and cost. More details regarding the availability and how to use the service will be coming soon.

I hope this bulletin answers your questions and clarifies most issues surrounding the MIRF process.

Thank you.

Kiumars Q Vadieli

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