From: David Myers
Sent: Monday, June 20, 2011 6:43 AM
To: Michael Perfetto; Michael Berryman; Michael Dorsey; Steve Cohen; Lisa Pehlke; Thad Demos; Nancy Baran; John Reed; Ara Aprahamian RPh; Soojung Chung; Alana Dundas; Cheryl De La Cruz; Patrick LaClair; Bob Miranda; Jinping McCormick; Rachelle Galant; Violet Wojtulewicz; Karen Stoedter
Subject: Oxymorphone Launch Preparation
Attachments: Fact Sheet Oxymorphone HCl Tablets.doc; Oxymorphone ER 7.5mg 100s HDMA 0228-3261-11.xls; Oxymorphone ER 15mg 100s HDMA 0228-3262-11.xls

Team,

I have attachedthe launch preparation documents that we will be discussing at this morning'smeeting. Please note that WAC and AWP pricing has not been finalized;therefore, the pricing segments have been left blank or have been labeled TBD. Iwill send out update documents once discussions surround pricing have beencompleted.

Thanks,

David

David Myers
SeniorManager, Products & Communications

actavis
think smart medicine

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New Product Fact Sheet:
Oxymorphone HCl Extended-Release Tablets 7.5 &15mg

Brand/Company: Opana® ER/ Marketed and Manufactured by Endo Labs
Generic Name: Oxymorphone Hydrochloride Extended-Release Tablets

Availability Date: July 15, 2011

Indication: Oxymorphone HCl ER Tablets are indicated for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.

TEE Rating AB to Opana® ER

Overall Market (all strengths)

Actual 12 Months Ending March 2011 Total Market Units (tablets):	49.8 MM
Projected 2011 Total Market Extended Units (tablets):	310 MM
Actual 12 Months Ending December 2010 Total Market Sales (IMS):	$318 MM

7.5 & 15mg strengths had sales of $22m, but brand discontinued these strengths in 03/2011.

Product

- **Opana® ER - 5mg, 7.5mg, 10mg, 15mg, 20mg, 30mg, and 40mg received approval June 22, 2006.** Marketed by Endo, manufactured by Novartis.
- Market volume has increased by 28%; dollar volume increased by 41% (year-over-year).
- Trade channel: 49% volume is via drug chains, 34% via Independents, 11% via Food Stores. LTC and Mail order comprise less than 5%.
- *Endo discontinued the 7.5mg and 15mg strengths in March 2011. This will present marketing challenges to Actavis.*

Generic Competition –

- Actavis received ANDA approval of the 7.5mg and 15mg on 12/13/2010.
- Although our settlement with Endo allows us to launch on 7/15, we do not have market exclusivity. Therefore, there may be as many as 3 generic competitors: Actavis, Impax, and an AG (Qualitest?).
- Impax was awarded ANDA approval on all strengths (including the 7.5 & 15mg) on 6/14/2010. However, we do not know if the terms of their settlement with the brand allow them to launch with us on 7/15/2011.
- Actavis has tentative approval on all remaining strength of the ER tablets.

Continued on next page.

Oxymorphone HCl Extended-Release Tablets 7.5 &15mg (continued)

Actavis Market Share Target: 50%

- To be manufactured in Elizabeth, Filed sizes 100ct & 500ct on both strengths. Will launch only the 100's.

Pricing

NDC#	Strength	Size	AWP	WAC
0228-3261-11	7.5mg	100's	$TBD	$TBD
0228-3262-11	15mg	100's	$TBD	$TBD

* Preliminary pricing, subject to change

Marketing Promotional Plans

Because Endo discontinued the 7.5 and 15mg strengths in March 2011, Actavis will be implementing a more aggressive promotional campaign for this launch. We currently plan to execute the following programs:

- A two wave **direct-mail campaign** to the top 10,000 prescribing doctors. The first wave is planned to coincide with our launch to bring awareness to prescribing doctors. A follow-up mailing is planned for a few weeks post-launch.
- **Direct Contact:** We will be utilizing the Kadian sales force to deliver sellsheets to known pain doctors they visit in their day-to-day promotion of Kadian. The sales team will be trained on Oxymorphone during their July meeting.
- **Journal advertising** to two segments of the industry:
  - Practical Pain Management – focused on pain specialists. Circulation: 45,000.
  - Pharmacy Times – focused on Pharmacists/Pharmacy buyers. Circulation: 163,500.
- **Email campaign** reaching a pharmacy audience of 87,000 addresses.

Produced as Natives

CHDMA Standard Pharmaceutical Product Information

☑ New Item ☐ Promotion/Deal ☐ Open Stock ☐ Post Launch Change Date: TBD

PRODUCT INFORMATION

Manufacturer/Broker Name: Actavis Elizabeth LLC Number: 00228
Rx Product Name: Oxymorphone HCl ER Tab CII 7.5mg ☐ NDA ☑ ANDA
Product ID Number: ☑ NDC 0228-3261-11 ☑ UPC/GTIN 3 0228-3261-11 7
Serialized? ☐ Yes ☐ No How? ☐ 2D ☐ RFID ☐ Pallet ☐ Case ☐ Item
Description: Gray round tablets, debossed with Acavis logo "(/" on one side and 261 on the other side
URL for additional product information:
Address: 200 Elmora Avenue
City, State, Zip: Elizabeth, NJ 07207
Key Contact: David Myers Email:
Phone Number: 1-888-925-2342 Fax:
Is the Product... ☐ A Direct Ship Item ☐ A Drop Ship Item
a Controlled Drug? ☑ Yes ☐ No If Yes, Schedule Number: II
ARCOS reportable? ☐ Yes ☑ No Biological? ☐ Yes ☑ No
Co-Licensed? ☐ Yes ☑ No Repackaged? ☐ Yes ☑ No
a Legend Device? ☐ Yes ☑ No Does the product contain DEHP? ☐ Yes ☑ No
Active ingredient, if product contains a drug: Oxymorphone Hydrochloride
Country of Origin: USA
Harmonization Code Number for International Shipping:
Is this product a Hazardous Material or Cytotoxic Agent? ☐ *Yes ☑ No
*If yes, provide additional information on page 2.
Attach copy of MATERIAL SAFETY DATA SHEET (MSDS) and PACKAGE INSERT

SPECIAL HANDLING AND STORAGE REQUIREMENTS

a. Temperature – Indicate the USP temperature range for this product.
- ☐ I. Freezer – between -25 and -10 C (-13° – 14° F)
- ☐ II. Cold – between 2 and 8 C (36° – 46° F)
- ☐ III. Cool – between 8 and 15 C (46° – 59° F)
- ☑ IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
- ☐ V. Excessive Heat – above 40 C (>104° F)
- ☐ VI. Other Temperature Range Requirement (write in)
- ☐ VII. No Requirement

b. Contact for temperature excursion questions:
Name: Number:

Is this product to be shipped to customers on ice? ☐ Yes ☑ No
Is this product to be shipped to customers on dry ice? ☐ Yes ☑ No

c. Special regulations for this product in certain states? ☐ *Yes ☐ No
Special returns requirements for this product? ☐ *Yes ☐ No

d. Store product upright? ☐ Yes ☑ No
Protect product from light? ☑ Yes ☐ No Other requirements?*
*Please provide additional information on page 2.

ADDITIONAL PRODUCT INFORMATION

Product Shape: round
Product Color: Gray
Product Imprint: "(/" on one side and 261 o
Is there a minimum order quantity? ☑ Yes ☐ No
If yes, how many? 12
Of what package type? ☐ Case ☐ Carton ☑ Item
Shelf life: 24 Months
Initial shelf life at launch (if diff't)

Whsl. Code #:
Fineline Code:
Is Item? ☐ Unit Dose ☐ Unit of Use
If Unit Dose, is item bar coded to unit dose for hospital scanning? ☐ Yes ☐ No

ITEM AND PACKING INFORMATION

Size/Strength/ Form	Unit of Sale	UPC Code	Mstr. Shpr.	Inner Case Pk	Wght. Lbs.	Cube	Dimensions Case	Dimensions Item	Dimensions Pallet	# Cases/ Pallet
100/ 7.5mg/ Tablet	☑ Bottle ☐ Box ☐ Glass Jar ☐ Ampule ☐ Other:	Case:	12	NA	Case: 1 lb 3oz	0.10 cuft (case)	Depth: 7.25"	Depth: 1.74"	Depth: 48"	480
		Carton:			Carton:		Height: 4.5"	Height: 2.98"	Height:	
		Item: 3 0228-3261-11 7			Item: 1.39 oz		Width: 5.50"	Width: 1.74"	Width: 40"	

For Generic Drug Products:
I. Orange Book: Rating: AB
II. Product Color: grey
III. Brand Name Equivalent: Opana ER
IV. Generic Name for Brand: Oxymorphone Hydrochloride Extended-release tablets

COST INFORMATION

	Regular Cost ($)	Purchase Allowance ☐ OI ☐ BB $	Purchase Allowance ☐ OI ☐ BB %	Distribution ☐ OI ☐ BB $	Distribution ☐ OI ☐ BB %	Invoice Cost ($)	Net Cost ($)	Mfr's AWP	Avg Retail Price ($)	SRP ($)	Excise Tax
DZ											
EA											
PPK											

This offer is made on a proportionally equal basis to all sellers' accounts completive with customer. Signature:

CHDMA Standard Pharmaceutical Product Information (Page 2)

HAZARDOUS MATERIAL INFORMATION

Is this product (check all that apply):

a. Cytotoxic? ☐ Yes ☑ No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? ☐ Yes ☑ No

- ☐ Carcinogen
- ☐ Reproductive Toxicant
- ☐ Both
- ☐ Warning appears on label

c. Contact Hazard? ☐ Yes ☑ No

d. Does this product require special clean-up instructions? ☐ Yes ☑ No

If yes, attach MSDS with special instructions

DANGEROUS GOODS SHIPPING INFORMATION

Is this product regulated for shipment by the DOT ☐ Yes ☑ No

(if yes, answer a-d below and provide MSDS)

a. DOT Hazard Class _____ b. UN/ID Number _____

c. Packing Group _____ d. Inhalation Hazard? ☐ Yes ☑ No

Is this product shipped utilizing an authorized DOT exception or Special Permit? ☐ Yes ☑ No (if yes, identify method below)

- ☐ Limited Quantity
- ☐ Consumer Commodity, ORM-D
- ☐ Small Quantity (49 CFR 173.4)
- ☐ Special Permit; DOT-SP _____
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101); SP# _____

Is the product restricted for air shipment?

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

STORAGE INFORMATION

Please check as appropriate for this product.

- ☐ Organic
- ☐ Inorganic
- ☐ Antineoplastic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ Aerosol; Identify NFPA Storage Level: ☐ Level 1 ☐ Level 2 ☐ Level 3
- ☐ Precursor Chemical (Describe below):
  - ☐ Ephedrine
  - ☐ Pseudoephedrine
  - ☐ Phenylpropanolamine
  - ☐ Iodine (≥2.2%)
  - ☐ Other: _____

PRODUCT INFORMATION

Does this product or its components have an MSDS? ☐ Yes ☑ No

(e.g., chemicals, solutions, products impregnated with solutions, batteries, drugs, etc.)

Attach a copy of MSDS or non-hazard letter.

ADDITIONAL INFORMATION

Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements?

HDMA Standard Pharmaceutical Product Information Form Instructions

(Last revised April 2009)

The information conveyed about new products has critical downstream implications, which affect the appropriate receiving, handling and storage at the distributor's facility and farther along in the supply chain. This **two-page** form has been expanded to include additional, more specific, special handling, storage, and temperature requirements that align with US Pharmacopeia ranges, as well as a reorganized section about shipping information for hazardous materials and dangerous goods. The form provides space to indicate whether a drug product has special regulations or returns requirements in certain states.

Please review each section on the two-page form and provide all relevant information and include only one product or promotion per form.
Use the *LEFT* mouse button to select check-boxes and highlight areas to type text or numbers.

New Item **Promotion/Deal** **Open Stock** **Post Launch Change**

Check the appropriate box to identify the purpose of the form.

New Item – Select if this product is new to the distributor as part of the pre-launch communications.
Promotion/Deal – Select if product is available as part of a promotion or deal package. [Product details have been previously communicated.]
Open Stock – Select if product is to be kept in stock.
Post Launch Change – Select if information previously communicated has changed or will change during the first year of a new product launch.

Product Information

Manufacturer/Broker Name and Number - Enter the manufacturer's corporate or division name. Also, most drug wholesaler/distributors assign vendor numbers to identify manufacturers. This number should be entered by the drug wholesale buyer.

Rx Product Name [1] - Enter complete product name, and indicate whether it is has a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) per Food and Drug Administration (FDA) guidance.

NDC/UPC Numbers - Indicate product's identification number [e.g. 10 digit National Drug Code (NDC) and/or 12 digit Universal Product Code (UPC)/ 14 digit Global Trade Identification Number (GTIN)] in space provided, as appropriate.

Serialized? – Indicate whether the product has been individually identified with a serial number. If so, indicated how (via 2D barcode or RFID tag) and to what level (pallet, case or item).

Product Description - Enter product description in space provided.

URL – Include web address for additional product information

Address - Manufacturer's corporate or divisional address. Include city, state and zip on the line following.

Key Contact - Name of key contact at headquarters level, e.g., V.P., Sales, National Account Manager, Director of Trade Relations, etc.

E-mail – Include e-mail address for key contact

Phone Number(s) - Enter '800' number, if applicable. Also, include key contact's direct phone number.

Fax - Enter fax number for key contact.

[1] This form was developed for the introduction of Rx products. There may be other information relevant for the introduction of over-the-counter (OTC) drugs (e.g. other bases for marketing) not referenced on this form.

Shipment Information - Indicate whether product is a direct or drop ship item.

Biological – Indicate whether the product is biological, defined in Section 351 of the *Public Health Service (PHS) Act* as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, ... applicable to the prevention, treatment, or cure of a disease or condition of human beings."

Controlled Drug - Indicate whether this product is a controlled substance and, if so, what Schedule (II, III, IV, or V) under the Controlled Substances Act (21 U.S.C. §801 et seq.) (CSA).

ARCOS Reportable - Indicate whether this product must be reported in the Drug Enforcement Administration's Office of Diversion Control's **A**utomation of **R**eports and **C**onsolidated **O**rders **S**ystem (ARCOS).

Co-Licensed? Is the product manufactured or marketed under an official collaborative licensing agreement?

Re-packaged? Is this a repackaged product? [Repackaging or otherwise changing the container, wrapper or labeling to further distribution]

Legend Device - Indicate if this product is a device registered with the Food and Drug Administration (FDA) through the PMA or 510K process and carries a statement such as "RX only" or "Caution; Federal (USA) law restricts this device to be used or sold unless on the order of a physician."

DEHP? Indicate whether the product contains Di (2-ethylhexyl) phthalate (DEHP), a plasticizer (softener) added to increase the flexibility of the polymer of most PVC medical devices such as IV bags or tubing.

Active Ingredient – An active ingredient (AI), also active pharmaceutical ingredient (API) or bulk active, is any component that is intended to furnish pharmacological activity. See 21 CFR 210.3(b)(7).

Country of Origin and Harmonization Code Number - Enter product's country of origin and harmonization code number for international shipping. All of the import and export codes used by the United States are based on the Harmonized Tariff System (HTS). See the Harmonized Tariff Schedule reference information published by the USITC:
http://hotdocs.usitc.gov/docs/tata/hts/bychapter/0901htsa.pdf

HAZMAT/Cytotoxic Agent - Indicate whether product is a Hazardous Material or Cytotoxic Agent, and provide additional information on page two of form, as appropriate.

***Material Safety Data Sheet (MSDS)** - Attach copy of product MSDS.

***Package Insert** - Attach product's Package Insert.

Additional Product Information

Product Shape/Color – Include the shape and color as listed on the package insert. Example "Oval / Purple"

Product Imprint – List imprint, if any. Example: "dp25"

Minimum Order Quantity - Indicate whether there is a minimum order quantity required and, if so, how many. Then indicate whether the minimum applies to Case, Carton, or Item?

Shelf Life - Indicate product's shelf life in months, and initial shelf life at launch, if it is different.

Wholesaler Code # - Entered by wholesaler/distributor.

Fineline Code - Entered by wholesaler/distributor.

Unit Dose/Unit of Use - Indicate if product is a unit dose or unit of use.

Unit Dose bar coding - If Unit Dose, indicate whether item is bar coded to the unit level.

*Include separate attachments.

Special Handling and Storage Requirements

a. Temperature - Indicate the USP temperature range for this product as indicated.

b. Temperature excursions – Indicate a contact name and phone number for questions.
Indicate whether the product is to be shipped on ice or dry ice.

c. Additional Requirements – Indicate whether there are special regulations for this product in certain states.
Indicate whether there are special returns requirements for this product.

Provide additional information on page 2.

Item and Packing Information

Size/Strength/Form – Size and strength may be stated in milligrams or as extra, medium, etc. Also, indicate form of product as required, e.g., tab cap, gel cap, etc.

Unit of Sale - Indicate the smallest unit of sale.

UPC Code - Enter Universal Product Code (UPC) numbers for case pack (master shipper), carton (inner-pack) and/or individual product item ("each.").

Master Shipper - Enter number of pieces in master shipper (case) pack.

Inner Case Pack - Enter number of pieces in a carton (inner case pack), where applicable.

Weight Lbs. - Enter weight in pounds for case, carton and item, as appropriate.

Cube - Enter cube dimensions here for case, carton and item, as appropriate.

Case Dimensions - Enter case dimensions by depth, height, and width.

Item Dimensions - Enter boxed, carded or loose item dimensions by depth, height and width.

Pallet Dimensions - Enter full pallet dimensions in depth, height and width.

# of Cases per Pallet - Enter number of full cases that make up a regular pallet load of this product.

Generic Drug Products - For generic products, provide the FDA Orange Book Rating, the product color, the brand name equivalent information and the generic name for the brand.

Cost Information

Regular Cost ($) - Enter regular dollar cost by dozen (dz.), each (ea.) and/or prepack (ppk.).

Purchase Allowance - Enter purchase allowance dollar figure and percentage figure, and check appropriate box as to whether allowances are available off-invoice (O.I.) or chargeback (B.B.).

Distribution Allowance - Enter distribution allowance dollar figure and percentage figure, and check appropriate box as to whether allowances are available off-invoice (O.I.) or chargeback (B.B.).

Invoice Cost ($) - $ regular cost minus $ purchase allowance.

Provide additional cost and price information for Net Cost, Manufacturer Average Wholesale Price (AWP), Average Retail Price, Suggested Retail Price (SRP) and Excise Tax.

Page Two Instructions - Please complete page 2 [Excel worksheet 2] as necessary.

Hazardous Material Information

This section of the form is intended to help pass along important product-specific information to assist all channel members in meeting hazardous material, dangerous goods shipping, and occupational health and safety regulatory requirements. **It is critical it be provided.**

Cytotoxic – Indicate whether the product is cytotoxic. Antineoplastic/Cytotoxic: A class of drug that is cell-killing or used to stop the spread of abnormal tissue (neoplasms). These are often used to treat cancers.

CA Prop. 65 Carcinogen or Reproductive Toxicant – Indicate whether the product is classified as a carcinogen under California's proposition 65. Proposition 65 regulates substances listed by California as causing cancer or birth defects or other reproductive harm.

Contact Hazard – Indicate whether this contains a contact-hazard chemical, an allergen or sensitizer when it meets any of the following:

Is so identified or described in the MSDS or on the label;

Is so identified or described in the medical or industrial hygiene literature; or

Is known or found to be an allergen or sensitizer.

Special Clean-up Instructions - Indicate whether product requires special clean-up instructions, and attach instructions on MSDS.

Attach copy of Material Safety Data Sheet (MSDS), if appropriate.

Dangerous Goods Shipping Information

Indicate whether the product is regulated for shipment by the US Department of Transportation (DOT) and if so, complete the following a – d:

a. Hazard Class: DOT classifies material into nine internationally recognized classes and two domestic-only classes. The classes are defined in 49 CFR 171.8 and are needed for storage and transport of the material. Class may be found in column 3 of the DOT Hazardous Substance Table 49 CFR 172.101.

b. UN/ID Number: This is the United Nations of North American identification number for a hazardous substance which is required for transporting the material. It may be found in column 4 of the DOT Hazardous Materials Table 49 CFR 172.101.

c. Packing Group –The packing group (designated in Roman numerals) prescribed for the material in column 5 in 49 CFR, Part 172.101 Table, indicating the degree of danger presented by the material. The shipper is responsible for determining the appropriate packing group.

d. Inhalation Hazard – Indicate whether the product is an inhalation hazard.

Indicate whether the product is shipped utilizing an authorized DOT exception or Special Permit. If yes, identify the method in the space provided. Select from the options listed as appropriate. [Limited Quantity; Consumer Commodity, ORM-D; Small Quantity (49 CFR 173.4); Special Permit; DOT-SP; Special Provision (listed in Column 7 of CFR 172.101)]

Indicate whether the product is restricted for air shipment, and check "Passenger," "Cargo," or "Passenger & Cargo" as appropriate.

Storage Information

Indicate as appropriate the classifications that impact product storage.

Organic/Inorganic: OSHA requires only compatible chemicals be stored, packaged and shipped together. Organic and inorganic substances must be separated. Organic substances contain carbon compounds. Inorganic substances do not involve organic life and are not products thereof, i.e., carbon.

Antineoplastic/Cytotoxic: A class of drug that is cell-killing or used to stop the spread of abnormal tissue (neoplasms). These are often used to treat cancers.

Corrosive - A product that contains chemicals that have the potential to react with or migrate from other hazardous materials. The reaction tends to dissolve or wear away gradually by a chemical action (e.g., rust).

Steroid/Androgen: A class of drug now regulated as controlled substances by federal and state governments. They are fat-soluble, organic compounds and hormones.

Oxidizer - A substance that combines with oxygen to form an oxide or induces another substance to oxidize.

Aerosol - Indicate whether product is packaged under pressure with gaseous propellant for release as an aerosol and requires special storage.

Aerosol Class - Aerosols are classed by the National Fire Protection Association as level one, two or three depending on the flammability and mix of the propellant. Level one is the least flammable, level three the most. Automotive products are typically level three.

Precursor Chemical - A chemical classified by the DEA in 21 CFR1310.02a that may be used in illegally manufacturing controlled substances. (Identify Precursor Chemical Type in next section of form).

Product Information

Indicate whether the product or its components have a Material Safety Data Sheet (MSDS), and attach a copy if so.
If you have a non-hazard letter exempting you from providing an MSDS, attach it.

Additional Information

Please provide any additional state requirements or other information as requested in the section.

Produced as Natives

CHDMA Standard Pharmaceutical Product Information

☑ New Item ☐ Promotion/Deal ☐ Open Stock ☐ Post Launch Change **Date:** TBD

PRODUCT INFORMATION

Manufacturer/Broker Name:	Actavis Elizabeth LLC — Number: 00228
Rx Product Name:	Oxymorphone HCl ER Tab CII 15mg — ☐ NDA ☑ ANDA
Product ID Number:	☑ NDC 0228-3262-11 ☑ UPC/GTIN3 0228-3262-11 4
Serialized?	☐ Yes ☐ No How? ☐ 2D ☐ RFID ☐ Pallet ☐ Case ☐ Item
Description:	White to off white round tablets, debossed with Acavis logo "(/" on one side and 262 on the other side
URL for additional product information:	
Address:	200 Elmora Avenue
City, State, Zip:	Elizabeth, NJ 07207
Key Contact:	Jinping McCormick — Email:
Phone Number:	1-888-925-2342 — Fax:
Is the Product...	☐ A Direct Ship Item ☐ A Drop Ship Item
a Controlled Drug?	☑ Yes ☐ No — If Yes, Schedule Number: II
ARCOS reportable?	☐ Yes ☑ No — Biological? ☐ Yes ☑ No
Co-Licensed?	☐ Yes ☑ No — Repackaged? ☐ Yes ☑ No
a Legend Device?	☐ Yes ☑ No — Does the product contain DEHP? ☐ Yes ☑ No
Active ingredient, if product contains a drug:	Oxymorphone Hydrochloride
Country of Origin:	USA
Harmonization Code Number for International Shipping:	
Is this product a Hazardous Material or Cytotoxic Agent?	☐ *Yes ☑ No

*If yes, provide additional information on page 2.

Attach copy of MATERIAL SAFETY DATA SHEET (MSDS) and PACKAGE INSERT

SPECIAL HANDLING AND STORAGE REQUIREMENTS

a. Temperature – Indicate the USP temperature range for this product.

- ☐ I. Freezer – between -25 and -10 C (-13° – 14° F)
- ☐ II. Cold – between 2 and 8 C (36° – 46° F)
- ☐ III. Cool – between 8 and 15 C (46° – 59° F)
- ☑ IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
- ☐ V. Excessive Heat – above 40 C (>104° F)
- ☐ VI. Other Temperature Range Requirement (write in)
- ☐ VII. No Requirement

b. Contact for temperature excursion questions: Name: Number:

Is this product to be shipped to customers on ice? ☐ Yes ☑ No

Is this product to be shipped to customers on dry ice? ☐ Yes ☑ No

c. Special regulations for this product in certain states? ☐ *Yes ☐ No

Special returns requirements for this product? ☐ *Yes ☐ No

d. Store product upright? ☐ Yes ☑ No

Protect product from light? ☑ Yes ☐ No Other requirements?*

*Please provide additional information on page 2.

ADDITIONAL PRODUCT INFORMATION

Product Shape	round
Product Color	white to off-white
Product Imprint	"(/" on one side and 262 o
Is there a minimum order quantity?	☑ Yes ☐ No
If yes, how many?	12
Of what package type?	☐ Case ☐ Carton ☑ Item
Shelf life:	24 Months
Initial shelf life at launch (if diff't)	
Whsl. Code #:	
Fineline Code:	
Is Item?	☐ Unit Dose ☐ Unit of Use
If Unit Dose, is item bar coded to unit dose for hospital scanning?	☐ Yes ☐ No

ITEM AND PACKING INFORMATION

Size/Strength/ Form	Unit of Sale	UPC Code	Mstr. Shpr.	Inner Case Pk	Wght. Lbs.	Cube	Dimensions Case	Dimensions Item	Dimensions Pallet	# Cases/ Pallet
100/ 15mg/ Tablet	☑ Bottle ☐ Box ☐ Glass Jar ☐ Ampule ☐ Other:	Case:	12	NA	Case: 1 lb 3oz	0.10 cuft (case)	Depth: 7.25"	Depth: 1.74"	Depth: 48"	480
		Carton:			Carton:		Height: 4.5"	Height: 2.98"	Height:	
		Item: 3 0228-3262-11 4			Item: 1.39 oz		Width: 5.50"	Width: 1.74"	Width: 40"	

For Generic Drug Products:

I. Orange Book: Rating: AB

II. Product Color: white to off-white

III. Brand Name Equivalent: Opana ER

IV. Generic Name for Brand: Oxymorphone Hydrochloride Extended-release tablets

COST INFORMATION

	Regular Cost ($)	Purchase Allowance ☐ OI ☐ BB $	Purchase Allowance ☐ OI ☐ BB %	Distribution ☐ OI ☐ BB $	Distribution ☐ OI ☐ BB %	Invoice Cost ($)	Net Cost ($)	Mfr's AWP	Avg Retail Price ($)	SRP ($)	Excise Tax
DZ											
EA											
PPK											

This offer is made on a proportionally equal basis to all sellers' accounts completive with customer. **Signature:**

CHDMA Standard Pharmaceutical Product Information (Page 2)

HAZARDOUS MATERIAL INFORMATION

Is this product (check all that apply):

a. Cytotoxic? ☐ Yes ☑ No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? ☐ Yes ☑ No

- ☐ Carcinogen
- ☐ Reproductive Toxicant
- ☐ Both
- ☐ Warning appears on label

c. Contact Hazard? ☐ Yes ☑ No

d. Does this product require special clean-up instructions? ☐ Yes ☑ No

If yes, attach MSDS with special instructions

DANGEROUS GOODS SHIPPING INFORMATION

Is this product regulated for shipment by the DOT ☐ Yes ☑ No

(if yes, answer a-d below and provide MSDS)

a. DOT Hazard Class _____ b. UN/ID Number _____

c. Packing Group _____ d. Inhalation Hazard? ☐ Yes ☑ No

Is this product shipped utilizing an authorized DOT exception or Special Permit? ☐ Yes ☑ No (if yes, identify method below)

- ☐ Limited Quantity
- ☐ Consumer Commodity, ORM-D
- ☐ Small Quantity (49 CFR 173.4)
- ☐ Special Permit; DOT-SP _____
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101); SP# _____

Is the product restricted for air shipment?

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

STORAGE INFORMATION

Please check as appropriate for this product.

- ☐ Organic ☐ Inorganic
- ☐ Antineoplastic ☐ Steroid/Androgen
- ☐ Corrosive ☐ Oxidizer
- ☐ Aerosol; Identify NFPA Storage Level: ☐ Level 1 ☐ Level 2 ☐ Level 3
- ☐ Precursor Chemical (Describe below):
  - ☐ Ephedrine
  - ☐ Pseudoephedrine
  - ☐ Phenylpropanolamine
  - ☐ Iodine (≥2.2%)
  - ☐ Other: _____

PRODUCT INFORMATION

Does this product or its components have an MSDS? ☐ Yes ☑ No

(e.g., chemicals, solutions, products impregnated with solutions, batteries, drugs, etc.)

Attach a copy of MSDS or non-hazard letter.

ADDITIONAL INFORMATION

Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements?

HDMA Standard Pharmaceutical Product Information Form Instructions

(Last revised April 2009)

The information conveyed about new products has critical downstream implications, which affect the appropriate receiving, handling and storage at the distributor's facility and farther along in the supply chain. This **two-page** form has been expanded to include additional, more specific, special handling, storage, and temperature requirements that align with US Pharmacopeia ranges, as well as a reorganized section about shipping information for hazardous materials and dangerous goods. The form provides space to indicate whether a drug product has special regulations or returns requirements in certain states.

Please review each section on the two-page form and provide all relevant information and include only one product or promotion per form.
Use the *LEFT* mouse button to select check-boxes and highlight areas to type text or numbers.

New Item **Promotion/Deal** **Open Stock** **Post Launch Change**

Check the appropriate box to identify the purpose of the form.

New Item – Select if this product is new to the distributor as part of the pre-launch communications.
Promotion/Deal – Select if product is available as part of a promotion or deal package. [Product details have been previously communicated.]
Open Stock – Select if product is to be kept in stock.
Post Launch Change – Select if information previously communicated has changed or will change during the first year of a new product launch.

Product Information

Manufacturer/Broker Name and Number - Enter the manufacturer's corporate or division name. Also, most drug wholesaler/distributors assign vendor numbers to identify manufacturers. This number should be entered by the drug wholesale buyer.

Rx Product Name [1] - Enter complete product name, and indicate whether it is has a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) per Food and Drug Administration (FDA) guidance.

NDC/UPC Numbers - Indicate product's identification number [e.g. 10 digit National Drug Code (NDC) and/or 12 digit Universal Product Code (UPC)/ 14 digit Global Trade Identification Number (GTIN)] in space provided, as appropriate.

Serialized? – Indicate whether the product has been individually identified with a serial number. If so, indicated how (via 2D barcode or RFID tag) and to what level (pallet, case or item).

Product Description - Enter product description in space provided.

URL – Include web address for additional product information

Address - Manufacturer's corporate or divisional address. Include city, state and zip on the line following.

Key Contact - Name of key contact at headquarters level, e.g., V.P., Sales, National Account Manager, Director of Trade Relations, etc.

E-mail – Include e-mail address for key contact

Phone Number(s) - Enter '800' number, if applicable. Also, include key contact's direct phone number.

Fax - Enter fax number for key contact.

[1] This form was developed for the introduction of Rx products. There may be other information relevant for the introduction of over-the-counter (OTC) drugs (e.g. other bases for marketing) not referenced on this form.

Shipment Information - Indicate whether product is a direct or drop ship item.

Biological – Indicate whether the product is biological, defined in Section 351 of the *Public Health Service (PHS) Act* as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, ... applicable to the prevention, treatment, or cure of a disease or condition of human beings."

Controlled Drug - Indicate whether this product is a controlled substance and, if so, what Schedule (II, III, IV, or V) under the Controlled Substances Act (21 U.S.C. §801 et seq.) (CSA).

ARCOS Reportable - Indicate whether this product must be reported in the Drug Enforcement Administration's Office of Diversion Control's **A**utomation of **R**eports and **C**onsolidated **O**rders **S**ystem (ARCOS).

Co-Licensed? Is the product manufactured or marketed under an official collaborative licensing agreement?

Re-packaged? Is this a repackaged product? [Repackaging or otherwise changing the container, wrapper or labeling to further distribution]

Legend Device - Indicate if this product is a device registered with the Food and Drug Administration (FDA) through the PMA or 510K process and carries a statement such as "RX only" or "Caution; Federal (USA) law restricts this device to be used or sold unless on the order of a physician."

DEHP? Indicate whether the product contains Di (2-ethylhexyl) phthalate (DEHP), a plasticizer (softener) added to increase the flexibility of the polymer of most PVC medical devices such as IV bags or tubing.

Active Ingredient – An active ingredient (AI), also active pharmaceutical ingredient (API) or bulk active, is any component that is intended to furnish pharmacological activity. See 21 CFR 210.3(b)(7).

Country of Origin and Harmonization Code Number - Enter product's country of origin and harmonization code number for international shipping. All of the import and export codes used by the United States are based on the Harmonized Tariff System (HTS). See the Harmonized Tariff Schedule reference information published by the USITC:
http://hotdocs.usitc.gov/docs/tata/hts/bychapter/0901htsa.pdf

HAZMAT/Cytotoxic Agent - Indicate whether product is a Hazardous Material or Cytotoxic Agent, and provide additional information on page two of form, as appropriate.

***Material Safety Data Sheet (MSDS)** - Attach copy of product MSDS.

***Package Insert** - Attach product's Package Insert.

Additional Product Information

Product Shape/Color – Include the shape and color as listed on the package insert. Example "Oval / Purple"

Product Imprint – List imprint, if any. Example: "dp25"

Minimum Order Quantity - Indicate whether there is a minimum order quantity required and, if so, how many. Then indicate whether the minimum applies to Case, Carton, or Item?

Shelf Life - Indicate product's shelf life in months, and initial shelf life at launch, if it is different.

Wholesaler Code # - Entered by wholesaler/distributor.

Fineline Code - Entered by wholesaler/distributor.

Unit Dose/Unit of Use - Indicate if product is a unit dose or unit of use.

Unit Dose bar coding - If Unit Dose, indicate whether item is bar coded to the unit level.

*Include separate attachments.

Special Handling and Storage Requirements

a. Temperature - Indicate the USP temperature range for this product as indicated.

b. Temperature excursions – Indicate a contact name and phone number for questions.
Indicate whether the product is to be shipped on ice or dry ice.

c. Additional Requirements – Indicate whether there are special regulations for this product in certain states.
Indicate whether there are special returns requirements for this product.

Provide additional information on page 2.

Item and Packing Information

Size/Strength/Form – Size and strength may be stated in milligrams or as extra, medium, etc. Also, indicate form of product as required, e.g., tab cap, gel cap, etc.

Unit of Sale - Indicate the smallest unit of sale.

UPC Code - Enter Universal Product Code (UPC) numbers for case pack (master shipper), carton (inner-pack) and/or individual product item ("each.").

Master Shipper - Enter number of pieces in master shipper (case) pack.

Inner Case Pack - Enter number of pieces in a carton (inner case pack), where applicable.

Weight Lbs. - Enter weight in pounds for case, carton and item, as appropriate.

Cube - Enter cube dimensions here for case, carton and item, as appropriate.

Case Dimensions - Enter case dimensions by depth, height, and width.

Item Dimensions - Enter boxed, carded or loose item dimensions by depth, height and width.

Pallet Dimensions - Enter full pallet dimensions in depth, height and width.

# of Cases per Pallet - Enter number of full cases that make up a regular pallet load of this product.

Generic Drug Products - For generic products, provide the FDA Orange Book Rating, the product color, the brand name equivalent information and the generic name for the brand.

Cost Information

Regular Cost ($) - Enter regular dollar cost by dozen (dz.), each (ea.) and/or prepack (ppk.).

Purchase Allowance - Enter purchase allowance dollar figure and percentage figure, and check appropriate box as to whether allowances are available off-invoice (O.I.) or chargeback (B.B.).

Distribution Allowance - Enter distribution allowance dollar figure and percentage figure, and check appropriate box as to whether allowances are available off-invoice (O.I.) or chargeback (B.B.).

Invoice Cost ($) - $ regular cost minus $ purchase allowance.

Provide additional cost and price information for Net Cost, Manufacturer Average Wholesale Price (AWP), Average Retail Price, Suggested Retail Price (SRP) and Excise Tax.

Page Two Instructions - Please complete page 2 [Excel worksheet 2] as necessary.

Hazardous Material Information

This section of the form is intended to help pass along important product-specific information to assist all channel members in meeting hazardous material, dangerous goods shipping, and occupational health and safety regulatory requirements. **It is critical it be provided.**

Cytotoxic – Indicate whether the product is cytotoxic. Antineoplastic/Cytotoxic: A class of drug that is cell-killing or used to stop the spread of abnormal tissue (neoplasms). These are often used to treat cancers.

CA Prop. 65 Carcinogen or Reproductive Toxicant – Indicate whether the product is classified as a carcinogen under California's proposition 65. Proposition 65 regulates substances listed by California as causing cancer or birth defects or other reproductive harm.

Contact Hazard – Indicate whether this contains a contact-hazard chemical, an allergen or sensitizer when it meets any of the following:

Is so identified or described in the MSDS or on the label;

Is so identified or described in the medical or industrial hygiene literature; or

Is known or found to be an allergen or sensitizer.

Special Clean-up Instructions - Indicate whether product requires special clean-up instructions, and attach instructions on MSDS.

Attach copy of Material Safety Data Sheet (MSDS), if appropriate.

Dangerous Goods Shipping Information

Indicate whether the product is regulated for shipment by the US Department of Transportation (DOT) and if so, complete the following a – d:

a. Hazard Class: DOT classifies material into nine internationally recognized classes and two domestic-only classes. The classes are defined in 49 CFR 171.8 and are needed for storage and transport of the material. Class may be found in column 3 of the DOT Hazardous Substance Table 49 CFR 172.101.

b. UN/ID Number: This is the United Nations of North American identification number for a hazardous substance which is required for transporting the material. It may be found in column 4 of the DOT Hazardous Materials Table 49 CFR 172.101.

c. Packing Group –The packing group (designated in Roman numerals) prescribed for the material in column 5 in 49 CFR, Part 172.101 Table, indicating the degree of danger presented by the material. The shipper is responsible for determining the appropriate packing group.

d. Inhalation Hazard – Indicate whether the product is an inhalation hazard.

Indicate whether the product is shipped utilizing an authorized DOT exception or Special Permit. If yes, identify the method in the space provided. Select from the options listed as appropriate. [Limited Quantity; Consumer Commodity, ORM-D; Small Quantity (49 CFR 173.4); Special Permit; DOT-SP; Special Provision (listed in Column 7 of CFR 172.101)]

Indicate whether the product is restricted for air shipment, and check "Passenger," "Cargo," or "Passenger & Cargo" as appropriate.

Storage Information

Indicate as appropriate the classifications that impact product storage.

Organic/Inorganic: OSHA requires only compatible chemicals be stored, packaged and shipped together. Organic and inorganic substances must be separated. Organic substances contain carbon compounds. Inorganic substances do not involve organic life and are not products thereof, i.e., carbon.

Antineoplastic/Cytotoxic: A class of drug that is cell-killing or used to stop the spread of abnormal tissue (neoplasms). These are often used to treat cancers.

Corrosive - A product that contains chemicals that have the potential to react with or migrate from other hazardous materials. The reaction tends to dissolve or wear away gradually by a chemical action (e.g., rust).

Steroid/Androgen: A class of drug now regulated as controlled substances by federal and state governments. They are fat-soluble, organic compounds and hormones.

Oxidizer - A substance that combines with oxygen to form an oxide or induces another substance to oxidize.

Aerosol - Indicate whether product is packaged under pressure with gaseous propellant for release as an aerosol and requires special storage.

Aerosol Class - Aerosols are classed by the National Fire Protection Association as level one, two or three depending on the flammability and mix of the propellant. Level one is the least flammable, level three the most. Automotive products are typically level three.

Precursor Chemical - A chemical classified by the DEA in 21 CFR1310.02a that may be used in illegally manufacturing controlled substances. (Identify Precursor Chemical Type in next section of form).

Product Information

Indicate whether the product or its components have a Material Safety Data Sheet (MSDS), and attach a copy if so.
If you have a non-hazard letter exempting you from providing an MSDS, attach it.

Additional Information

Please provide any additional state requirements or other information as requested in the section.