A subsidiary of Watson Laboratories, Inc.

TO: Call Center Operation

FROM: Ella David CCO Trainer

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SUBJECT: DEA Excess/Controlled Substance New Product Launch

SUBJECT: Suspicious Orders of Controlled Drugs

DEA Excess/Controlled Substance New Product Launch

We are in the process of updating the department policy regarding "Suspicious Controlled Drug Order Investigation Report". The following section will be added.

In the case where we have launched a new controlled substance, we realize there is no purchase history recorded for the product and therefore it is impossible for the computer to come up with a twelve-month average and then flag the order if it is above this average. Currently every order is flagged in error as excessive and is considered to be a "Suspicious Controlled Drug Order". In effort to streamline the order process in this scenario, we will not require you to send the "Suspicious Controlled Drug Order Investigation Report", noting that the product is in DEA Excess to the customer for explanation and approval prior to management review.

As usual, Data Entry will issue the "Suspicious Order Investigation Report" to Mary Woods or myself noting "Initial Order" (Order Entry must check to make sure no prior orders were entered for this customer on this product, and then note "Initial Order"). We will review each order before it is released and processed. In the instance the order is deemed suspicious due to the quantity ordered for the size customer placing the order, you will be asked to contact the customer and follow the standard procedure to have the order approved and released.

Suspicious Orders of Controlled Drugs

Order Process will receive orders through faxes and EDI. Once these order(s) are entered the IS/Computer system will compile a past history of control substance drug products ordered by each customer to establish a notmal size order frequency.

If a processed order generates a DEA excessive order flag (currently scheduled quantity may cause DEA excesses reporting) due to more frequent or larger than the normal order pattern, Order Processing will generate a Suspicious Controlled Drug Order Investigation Report W-09-006. (see form next page)

These Suspicious Drug Order Investigation Report (W-09-006) will have the three month average on each product (s), purchase order number (PO), if EDI it will have the EDISO number, customer name, complete address, DEA number and reason for suspicion.

The Suspicious Controlled Drug Investigation Report W-09-006, is sent to Customer Support Rep. (CSR) via email. The CSR will review the investigation report, contact the customer to confirm the quantity and verify the reason for a larger pr more frequent order. Once this investigation report is confirmed and verified by the customer, the investigation report is signed by the CSR and submitted to management for review.

Management determines if the order does or does not classify as suspicious.

If a valid reason based on objective criteria does not exist, the order will be deemed as a suspicious order and will not be filled. The DEA will be notified.

If the order is valid, confirmed and signed by the management, the investigation report W-09-0006 is returned to Order Process.

Order process will file a copy of the investigation report W-09-006 with the customer's purchase order, in the suspicious order record file.