



ABBOTT

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FACSIMILE NO. (301) 827-0951

February 2, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20857

Re: [Docket Nos. 92N-0297 and 88N-0258]
Comments to PDMA Final Rule [Federal Register: December 3, 1999]

Dear Sirs or Madams:

Per the Agency's request, please note the enclosed comments from Abbott Laboratories regarding the referenced final rule revising the Prescription Drug Marketing Act. These comments are over and above comments previously received by FDA regarding this final rule. Abbott is in substantial agreement with such previous comments made by industry, though they are not repeated here. Abbott is an integrated worldwide manufacturer of healthcare products employing more than 54,000 people around the world with manufacturing sites in 35 countries.

Date of Implementation:

Given that the healthcare industry relies heavily on outside resources for the movement and delivery of prescription drug samples, and given that outside contractors are frequently employed to maintain tracking and accounting databases for such product, we recommend that the date of required implementation of the final rule be December 3, 2001 instead of December 3, 2000. The computer-based support systems used by manufacturers, common carriers, database contractors and associated state authorities will require considerable modification to incorporate key data elements prescribed by the final rule. These systems upgrades, along with associated procedural upgrades and interfaces that must be coordinated between affected parties, is a substantial and potentially costly undertaking.

92N-0297

OB 2



State Verification of Practitioner's License:

Clarify Sections 203.30(a)(2) and 203.31(a)(2) to require retrospective State verification of practitioner's licenses, instead of prospective verification. Retrospective verification will avoid delays in particular circumstances involving newly licensed practitioners - who will not be evaluated by the State, typically, until the State conducts its annual database update, or until the manufacturer submits a particular notification and request to the State for a newly licensed practitioner on an individual basis.

Prospective State verification of newly licensed practitioners would therefore be quite cumbersome for the State and result in significant delays and interruptions in the manufacturer's ability to conduct a uniform sampling program to all targeted licensed practitioners.

FOI Regarding Individual Falsification of Records:

Concern exists for occasions whereupon the manufacturer suspects falsification, reports a suspect individual to the FDA, and subsequently (as the result of a complete investigation) determines that the suspect individual did not falsify records. Concern also exists that manufacturers be able to acquire FDA listings of individuals who have been identified and reported to FDA with suspicion of falsification of records - in order that such individuals may be screened in the event they apply for similar employment with another manufacturer.

Please clarify the methods used in processing such notifications by manufacturers; in archiving such information (or rescinding it, in the case of mistaken or premature notifications by the manufacturer); and also with regard to publishing current listings of individuals who are considered by manufacturers to have falsified documentation.

Meaning of Receipt Signatures:

While Section 503 of the Act is understood to address a specific need for a system whereby mail or common carrier distributions require the recipient of a drug sample to execute a written receipt, Section 203.30(c) can be interpreted that such distributions undergo a physical inventory of drug sample product by the recipient, along with the confirmation of a lot of secondary data, at the point of written receipt. This seems an impractical exercise for healthcare professionals to undertake on a routine basis, and appears more focused on the detection of potential shipping errors than circumstances of diversion.



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Please contact Abbott Corporate Regulatory Affairs, Department 387 at
(847) 937-9404 with any questions or clarification regarding these comments.

Sincerely,

Mark M. Silverberg, Director
Policy & Regulatory Evaluation
Corporate Regulatory & Quality Science, D-387

HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CROSS REFERENCE SHEET

Docket Number/Item Code: 92N-0297/OB 2

See Docket Number/Item Code: 88N-0258/OB 7

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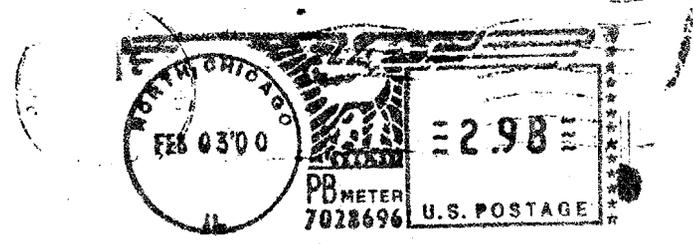
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RETURN RECEIPT REQUESTED

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