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November 16, 2001

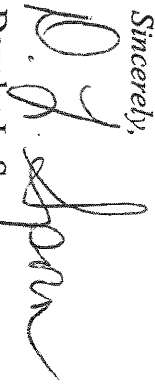
DOCKETS MANAGEMENT BRANCH (HFA-305)
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5630 Fishers Lane, Room 1061
Rockville, MD 20852

Ref: Docket No. 01D-0278 "Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research" Draft Guidance.

Abbott Laboratories is very pleased to have the opportunity to provide comments on the draft guidance for industry "Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research".

We thank the Agency for your consideration of our comments. Should you have any question, please contact Ivone Takenaka, PhD. at (847)-935-9011 or by FAX at 847-938-3106.

Sincerely,


Douglas L. Sporn

01D-0278

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November 16, 2001

**COMMENTS ON
Submitting Type V Drug Master Files to the
Center for Biologics Evaluation and Research Draft Guidance**

DOCKET No. 01D-0278

Abbott appreciates the draft guidance on Submitting Type V DMF to CBER and commends the Agency on the efforts to provide guidelines to industry on Drug Master File submissions. The following are our comments.

COMMENTS

III. OTHER TYPES OF DMFs

Abbott believes the submission of a letter of intent prior to submitting a DMF for information other than that covered under section II of this guidance, provides a better management of resources by the industry since the Agency may indicate that a DMF is not required. However, clarifications are needed as to how the Agency will handle proprietary information that may be included in the BLA and should not become public.

IV. UPDATING DMFs.

The DMF update interval specified in this section is ambiguous and subject to various interpretations. Abbott recommends revising this section to be consistent and similar with the requirement for NDA annual reports. That is, require DMFs to be updated annually and submitted within 60 days of the original submission date, similar to NDA annual reports which must be submitted within 60 days of the approval date.

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FedEx USA Airbill
Express

FedEx
Tracking
Number

831436956710

0215

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Recipient's Copy

1 From This portion can be removed for Recipient's records.

Date 11-19-01 FedEx Tracking Number 831436956710

Sender's Name Ivone Takenaka Phone 847 937-7987

Company ABBOTT LABS 387 6C

Address 100 ABBOTT PARK RD

City ABBOTT PARK State IL ZIP 60064

2 Your Internal Billing Reference

3 To

Recipient's Name T. Williams Phone 301 327-6210

Company Docket Management Branch

Address 5000 FREDERICK BLVD

City Rockville State MD ZIP 20852



0194034838

4a Express Package Service

FedEx Priority Overnight Next business morning

FedEx Standard Overnight Next business afternoon

FedEx 2Day Second business day

FedEx Express Saver Third business day

NEW FedEx Extra Hours Later drop-off with next business afternoon delivery for select locations

Packages up to 150 lbs. Delivery commitment may be later in some areas.

FedEx First Overnight Earliest next business morning delivery to select locations

4b Express Freight Service

FedEx 1Day Freight* Next business day

FedEx 2Day Freight Second business day

FedEx 3Day Freight Third business day

Packages over 150 lbs. Delivery commitment may be later in some areas.

5 Packaging

FedEx Envelope*

FedEx Pak* Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak

Other Pkg. Includes FedEx Box, FedEx Tube, and customer pkg.

* Declared value limit \$500

6 Special Handling

SATURDAY Delivery Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes

HOLD Weekday at FedEx Location Not available for FedEx First Overnight

HOLD Saturday at FedEx Location Available only for FedEx Priority Overnight and FedEx 2Day to select locations

Include FedEx address in Section 3.

Does this shipment contain dangerous goods? One box must be checked.

No Yes As per attached Shipper's Declaration

Yes Shipper's Declaration not required

Dry Ice Dry Ice, 9 UN 1845 x kg

Cargo Aircraft Only

Payment Bill to:

Sender Acct. No. in Section 4 will be billed.

Recipient Third Party Credit Card Cash/Check

Enter FedEx Acct. No. or Credit Card No. below. Obtain Recip. Acct. No.

Total Packages 1 Total Weight 1.0

Our liability is limited to \$100 unless you declare a higher value. See the FedEx Service Guide for details.

8 Release Signature Sign to authorize delivery without obtaining signature.

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

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