



ABBOTT LABORATORIES
Corporate Regulatory and Quality Science

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July 26, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Ref: Docket No. 02N-0215, OC 2002128. Agency Information Collection Activities; Proposed Collection; Comment Request; Export of FDA Regulated Products--Export Certificates.

Abbott Laboratories is very pleased to have the opportunity to provide comments on the Agency Information Collection Activities; Proposed Collection; "Export of FDA Regulated Products - Export Certificates", published in the Federal Register on May 30, 2002.

Abbott commends the Agency on their efforts on setting up provisions to ease restrictions on exportation of the FDA regulated unapproved products.

The Health Authorities from many international countries require specialized certificates, such as, certificates of free sale, health certificates, certificates for exportability, certificates on good manufacturing practices and on raw material origin, for the purpose of registration or manufacturing of nutritional products, human drugs and other medicinal products in their countries. Other countries Health Authorities also issue these types of documents. Countries requiring these certificates look to governmental acceptance of products, in which they import, for health product safety and security reasons.

Support by the FDA to issue specialized certificates enhances communications and international trade and insure that products regulated by the Agency are safe to public domestically, as well as, internationally.

We appreciate the Agency's efforts in supplying most of these documents in a timely manner, with the exception of the certificates for nutritionals (COFS) and the Declaration of GMP, which take usually about 3 months to be issued. We believe issuing these documents electronically would be to the Agency's advantage in terms of time and resources spent.

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Abbott Laboratories fully supports and finds the Agency activities on the requirements imposed on firms that intend to export to countries that require an export certificate as a condition of entry for FDA regulated products, extremely important and necessary

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

Sincerely,



Douglas L. Sporn
Divisional Vice-President
Corporate Regulatory Affairs

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FedEx USA Airbill
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Form
I.D. No.

0215

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1 From This portion can be removed for Recipient's records.
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 Sender's Name: S. VITEK Phone: 847 937-1454
 Company: ABBOTT LABS 17-387
 Address: 100 ABBOTT PARK RD
 City: ABBOTT PARK State: IL ZIP: 60064

2 Your Internal Billing Reference

3 To
 Recipient's Name: DOCKETS MGMT BRANCH
 Company: FDA
 Address: 5630 FISHERS LANE RM 1061
 HFA-305
 City: ROCKVILLE State: MD ZIP: 20852



0199963184

4a Express Package Service
 FedEx Priority Overnight Next business morning
 FedEx Standard Overnight Next business afternoon
 FedEx First Overnight Earliest next business morning delivery to select locations
 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

4b Express Freight Service
 FedEx 1Day Freight* Next business day
 FedEx 2Day Freight Second business day
 FedEx 3Day Freight Third business day

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.

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
 Does this shipment contain dangerous goods?
 No Yes As per attached Shipper's Declaration
 Yes Shipper's Declaration not required
 Dry Ice Dry Ice, 5, UN 1845 x kg
 Cargo Aircraft Only

7 Payment Bill to:
 Sender Acct. No. in Section 1 will be billed.
 Recipient Third Party Credit Card
 Obtain Recip. Acct. No. Cash/Check

Total Packages: _____ Total Weight: _____ Total Charges: _____
 Credit Card Auth. _____

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.
Questions? Visit our Web site at fedex.com
 or call 1.800.Go.FedEx® 800.463.3339.
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