



**ROSS PRODUCTS DIVISION • ABBOTT LABORATORIES**

625 CLEVELAND AVENUE • COLUMBUS, OHIO 43215-1724 • (614) 624-7677

7469 '00 JUL 24 AB 49

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

July 21, 2000

Re: Docket No. 00N-1034  
Medical Devices; Device Tracking

Dear Sir:

The Ross Products Division of Abbott Laboratories hereby submits the enclosed comments on the subject proposed rule as published in the *Federal Register* dated April 25, 2000.

The proposed rule was offered as making only conforming amendments as required by Section 519(e) of the Federal Food, Drug and Cosmetic Act and FDAMA '97, and other non-substantive revisions to remove outdated references and simplify terminology. However, we believe the comments made in the preamble to the proposed rule will have a significant impact on the application of the device tracking rules to enteral feeding pumps.

On FR page 24145, FDA expressed its concern about which infusion pumps must be tracked. The Agency commented that the February 1999 device tracking guidance caused uncertainty concerning which infusion pumps must be tracked. The February 1999 guidance identified "infusion pumps, except those designated and labeled for use exclusively for fluids with low potential risks, such as enteral feeding or anti-infectives" as types of pumps which are subject to tracking; however, the current FDA proposal would encompass a larger category of devices, namely "electromechanical infusion pumps used outside device user facilities." This expansion would, again, make enteral feeding pumps which are electromechanical in nature, subject to tracking, while unfairly exempting enteral feeding pumps which are not electromechanical.

00N-1034

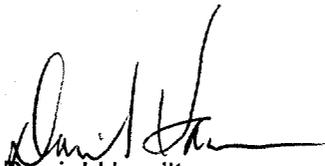
C  
C 1

Docket No. 00N-1034  
Medical Devices; Device Tracking  
Page 3

administration, the device must be so labeled and tracked. For devices that are indicated for both low-risk and high-risk indications, the manufacturer must then be prepared to track the high-risk applications. FDA would serve itself, the public health and industry better by delineating types of high-risk or low-risk intended uses for which tracking would or would not be ordered, rather than trying to single out certain types of infusion pump operating technology.

Therefore, we request that FDA reiterate and endorse in the preamble to the final rule the concept of using intended use, not operating technology, as the primary factor in determining which infusion pumps must be tracked, and further to consider amending the guidance on device tracking, dated January 24, 2000, to reflect this opinion.

Sincerely,



Daniel Hamilton  
Manager, Device Regulatory Affairs  
614-624-3743

131  
400  
+

**FedEx** USA Airbill FedEx Tracking Number **813866651027**

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

Date **7/21/00** FedEx Tracking Number **813866651027**

Sender's Name **DAN HAMILTON** Phone **614 624-6283**

Company **ROSS LABORATORIES**

Address **6480 BUSCH BLVD FL 1** **BU3**

City **COLUMBUS** State **OH** ZIP **43229**

**2 Your Internal Billing Reference** **444-102115**

**3 To** Recipient's Name **DOCUMENTS MANAGEMENT BRANCH**

Company **FOOD & DRUG ADMINISTRATION**

Address **5630 FISHERS LANE, ROOM 1061**

To "HOLD" at FedEx location print FedEx address here.  
City **ROCKVILLE,** State **MD** ZIP **20852**



Form No. **0215** Recipient's Copy

**4a Express Package Service** Packages up to 150 lbs. Delivery commitment may be later in some areas.

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  
\* FedEx Letter Rate not available Minimum charge: One-pound rate

**4b Express Freight Service** Packages over 150 lbs. Delivery commitment may be later in some areas.

FedEx 1Day Freight\* Next business day  FedEx 2Day Freight Second business day  FedEx 3Day Freight Third business day  
\* Call for Confirmation: \_\_\_\_\_

**5 Packaging** \* Declared value limit \$500

FedEx Letter\*  FedEx Pak\*  Other Pkg. Includes FedEx Box, FedEx Tube, and customer pkg.

**6 Special Handling**

Saturday Delivery Available for FedEx Priority Overnight and FedEx 2Day to select ZIP codes  Sunday Delivery Available for FedEx Priority Overnight to select ZIP codes  HOLD Weekday at FedEx Location Available for FedEx Priority Overnight and FedEx 2Day to select locations  HOLD Saturday at FedEx Location Available for FedEx Priority Overnight and FedEx 2Day to select locations

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  
Dangerous Goods cannot be shipped in FedEx packaging.  Cargo Aircraft Only

**7 Payment Bill to:** Enter FedEx Acct. No. or Credit Card No. below.  Obtain Recip. Acct. No.

Sender Acct. No. in Section 1 will be billed  Recipient  Third Party  Credit Card  Cash/Check

Total Packages \_\_\_\_\_ Total Weight \_\_\_\_\_ Total Charges \_\_\_\_\_  
Credit Card Auth. \_\_\_\_\_  
\*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.  
Questions? Call 1-800-Go-FedEx (800-463-3339)  
Visit our Web site at www.fedex.com  
Rev. Date 1/98/Part #154813G-©1994-98 FedEx-PRINTED IN U.S.A. GBFE 7/99

RECIPIENT: PEEL HERE

0106438251

359