

HUESTISMEDICAL

March 18, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., rm. 1-23
Rockville, MD 20857

0520 '98 MAR 23 A10:03

Dear Sirs:

Thank you for the opportunity to submit comments in response to the ANPR concerning Refurbishers, Rebuilders, Reconditioners, Servicers, and "As Is" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Request for Comments and Information. (Docket number 97N-0477)

Our American Radiographics and Pro-Tronics groups have a long, successful history of Reconditioning/Rebuilding medical devices and providing them to the American public. We attribute our continued longevity and success to providing quality products guided by Good Manufacturing Practices and applicable policy guidelines. Strong customer satisfaction and our unblemished safety records further validate our expertise and qualifications in this field.

The competitive nature of the medical marketplace has created an evolution in size and complexity that is often confusing to prospective buyers of remarketed medical devices. We believe customers perceive the categories of "refurbishers," "rebuilders," and "reconditioners," of medical devices performing similar, if not identical activities. It is this perceived lack of definition that should be identified and revised to prevent confusion to prospective buyers.

We believe that the FDA has appropriately defined the terms, "refurbisher," "as is" remarketer, and "servicer." We also believe that the current level of regulatory controls that should be applied to persons who remarket devices is adequate. In addition, we would suggest that "refurbishers" should be held to the same standard as "reconditioners/rebuilders" due to comparable function, possible overlap, and foreseeable loopholes that some refurbishers may take advantage of.

We would also suggest that clear definitions of these levels and approaches to remarketing be publicized to ensure that the marketplace has a full understanding of the terms and processes involved. By publicizing the definitions we can accomplish two important things to protect buyers of remarketed devices. Firstly, buyers will be able to differentiate between and identify devices in a standardized manner. Secondly, a paper trail can be established to create distributor accountability.

As previously stated, we believe that "refurbishers" must register, list and comply with all CGMP requirements. We would not argue with any controls that the FDA would propose for "servicers" and "as is" remarketers.

Thank you again for allowing us to comment on this ANPR. We acknowledge that the FDA may have a broader scope of consideration for other medical devices that may require additional regulation, and appreciate the opportunity to offer insight as it relates to our field of expertise. We look forward to your decision.

Sincerely,



Peter C. Martin
President, Huestis Medical

HUESTISMEDICAL

March 18, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., rm. 1-23
Rockville, MD 20857

Dear Sirs:

Thank you for the opportunity to submit comments in response to the ANPR concerning Refurbishers, Rebuilders, Reconditioners, Servicers, and "As Is" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Request for Comments and Information. (Docket number 97N-0477)

Our American Radiographics and Pro-Tronics groups have a long, successful history of Reconditioning/Rebuilding medical devices and providing them to the American public. We attribute our continued longevity and success to providing quality products guided by Good Manufacturing Practices and applicable policy guidelines. Strong customer satisfaction and our unblemished safety records further validate our expertise and qualifications in this field.

The competitive nature of the medical marketplace has created an evolution in size and complexity that is often confusing to prospective buyers of remarketed medical devices. We believe customers perceive the categories of "refurbishers," "rebuilders," and "reconditioners," of medical devices performing similar, if not identical activities. It is this perceived lack of definition that should be identified and revised to prevent confusion to prospective buyers.

We believe that the FDA has appropriately defined the terms, "refurbisher," "as is" remarketer, and "servicer." We also believe that the current level of regulatory controls that should be applied to persons who remarket devices is adequate. In addition, we would suggest that "refurbishers" should be held to the same standard as "reconditioners/rebuilders" due to comparable function, possible overlap, and foreseeable loopholes that some refurbishers may take advantage of.

We would also suggest that clear definitions of these levels and approaches to remarketing be publicized to ensure that the marketplace has a full understanding of the terms and processes involved. By publicizing the definitions we can accomplish two important things to protect buyers of remarketed devices. Firstly, buyers will be able to differentiate between and identify devices in a standardized manner. Secondly, a paper trail can be established to create distributor accountability.

As previously stated, we believe that "refurbishers" must register, list and comply with all CGMP requirements. We would not argue with any controls that the FDA would propose for "servicers" and "as is" remarketers.

Thank you again for allowing us to comment on this ANPR. We acknowledge that the FDA may have a broader scope of consideration for other medical devices that may require additional regulation, and appreciate the opportunity to offer insight as it relates to our field of expertise. We look forward to your decision.

Sincerely,



Peter C. Martin
President, Huestis Medical

FedEx USA Airbill

FedEx Tracking Number

801723552146

0200

Form I.D. No.

SPH32
Recipient's Copy

1 From
Date 3/20/98



Sender's Name John O'Flaherty Phone (401) 253-5500

Company HUESTIS MACHINE CORP

Address 68 BUTTONWOOD AVE

City BRISTOL State RI ZIP 02809

2 Your Internal Billing Reference Information

3 To
Recipient's Name DOCKETS MANAGEMENT BRANCH (HFA-305) Phone (301) 594-4692

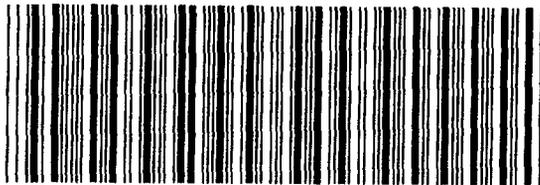
Company FOOD & DRUG ADMINISTRATION

Address 12420 PARKLAWN DR., RM 1-23

City ROCKVILLE State MD ZIP 20857

For HOLD at FedEx Location check here
 Hold Weekday (Not available with FedEx First Overnight)
 Hold Saturday (Available for FedEx Priority Overnight and FedEx 2Day only) (Not available at all locations)

For Saturday Delivery check here
 (Extra Charge. Not available to all locations) (Available for FedEx Priority Overnight and FedEx 2Day only)



8 0 1 7 2 3 5 5 2 1 4 6

4a Express Package Service Packages under 150 lbs. Delivery commitment may be later in some areas.
 FedEx Priority Overnight (Next business morning)
 FedEx Standard Overnight (Next business afternoon)
 FedEx 2Day* (Second business day)
 FedEx Express Saver* (Third business day)

FedEx First Overnight (Earliest next business morning delivery to select locations) (Higher rates apply)
*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 Overnight Freight (Next business day)
 FedEx 2Day Freight (Second business day)
 FedEx Express Saver Freight (Up to 3 business days)
(Call for delivery schedule. See back for detailed descriptions of freight services.)

5 Packaging
 FedEx Letter (Declared value limit \$500)
 FedEx Pak
 FedEx Box
 FedEx Tube
 Other Pkg.

6 Special Handling
Does this shipment contain dangerous goods? Yes (As per attached Shipper's Declaration) Yes (Shippers Declaration not required)
 Dry Ice (Dry Ice, 9 UN 1845 III) x kg. 904 CA **Cargo Aircraft Only** (Dangerous Goods Shipper's Declaration not required)

7 Payment
Bill to: **Sender** (Account no. in section 7 will be billed) **Recipient** (Enter FedEx account no. or Credit Card no. below) **Third Party** **Credit Card** **Cash/Check** **Obtain Recipient FedEx Account No.**



Total Packages _____ Total Weight _____ Total Declared Value* \$ _____ Total Charges \$ _____

*When declaring a value higher than \$100 per shipment, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY section for further information. Credit Card Auth. _____

8 Release Signature
John O'Flaherty

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.

Questions?
Call 1-800-Go-FedEx (800)463-3339

287

003385847 8

WCSL 0997
Rev. Date 5/97
Part #150364
©1994-97 FedEx
PRINTED IN U.S.A.