



Getinge/Castle, Inc.
1777 East Henrietta Road
Rochester, New York 14623-3133

Tel 716-475-1400
Fax 716-272-5291

97N-0477

January 15, 1998

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

Ref.: Docket No. 97N-0477

Dear Sir,

Getinge/Castle respectfully submits comments as requested in the December 23, 1998 ANPR for Refurbishers, Rebuilders, Reconditioners, Servicers and "As-Is" Remarketers of Medical devices. As a medical device manufacturer of sterilizers, surgical lights, surgical tables and allied healthcare products, we are concerned that if the definitions and the minimum regulatory compliance approach were to be implemented, that the current regulatory safeguards for the consumer will be significantly diminished.

We base the above statement on the following assumptions:

- That most, if not all, sterilizers currently sold as refurbished are rebuilt to a product design or specification different than when manufactured, thus significantly changing the product and,
- that there appears to be inadequate regulatory enforcement of medical device labeling requirements, especially for Remarketers, creating a double enforcement standard,
- that Refurbishers routinely violate labeling requirements.

Attached are several letters and faxes sent by me over the last 18 months requesting FDA assistance in verifying labeling claims of several Remarketers. We still see some Remarketers advertising remanufactured sterilizers for sale without being a registered facility or having 510(k) clearances. Additionally, we have attached an internal company communication detailing Medical Device regulatory requirements. It was sent our field personnel with the intent of informing them about device law.

97N-0477

C2

Page 2

The revisions under consideration in the ANPR (page 67013) should also include provisions for cGMP, facility registration and pre-market clearance. It's our belief that there should be only three categories. They are:

- Medical Device manufacturers
- Remanufacturer of medical devices
- "AS-IS" Remarketers

Definitions

Consumers would then understand that new medical devices (i.e. sterilizers) and remanufactured devices were built to a "standard of quality" and labeled according the medical device regulations. They would further understand when purchasing a medical device labeled "as-is." The name and definition are self descriptive. Finally, consumers could have confidence that new or remanufactured medical devices were built to performance standards and labeled properly.

Safety and Performance Problems

Steam sterilizers, used in healthcare settings, process medical devices for patient use. They are design, built and tested to AAMI standards. Consumers can have confidence that if they follow manufacture's written instruction for time and temperature and packaged/loaded the items appropriately, the load will be ready for patient use. They can not have the same confidence if they were to use a refurbished sterilizer, field engineered by a Remarketers to an unknown standard. New and remanufactured sterilizer are labeled by national test labs to recognized electrical standards (i.e. UL-544). A refurbished sterilizer should have the electrical safety label removed prior to resale unless the product meets the original specification, which typically it does not.

Level of Regulatory Control

The revision levels under consideration will create a double standard. Original device manufacturers must follow all the requirements. Considering the current low level of regulatory compliance by Remarketers, the lack of enforcement by the FDA and the need for equal public health protection, we urge the same regulatory requirements for new and remanufactured medical device. The exception would be "as-is."

If our recommendations are adopted, public health will be protected.

Sincerely,



Thomas K. "Chip" Moore
Senior Market Manager

cc: B. Von Kaenel

(Exhibits Enclosed)

Exhibits Attached

1. Exhibit I 12/23/97 Fax to the FDA, with proposal from Mercks Corp. and HPN Advertisement, dated December 1997
2. Exhibit II 7/16/97 Fax to the FDA, with Advertisement
3. Exhibit III Copy of Ad and phone call to the FDA in LA about Lancer Medical.
4. Exhibit IV 7/10/96 letter to the FDA
5. Exhibit V Sales Bulletin 55-96, dated 9/16/96

Exhibit I

MODE = MEMORY TRANSMISSION START=DEC-23 09:21 END=DEC-23 09:31

FILE NO. = 009

NO.	COM	ABBR/NTWK	STATION NAME/ TELEPHONE NO.	PAGES	PRG.NO.	PROGRAM NAME
001	OK		313015944610	004/004		

-MDT CASTLE CORP. -

***** -716 272 5291 - ***** 716 272 5291- *****

	Getinger/Castle, Inc.	Tel 716-272-5123
	1777 E. Henrietta Road	Fax 716-272-5291
	Rochester, NY 14623-3133	

◆◆◆◆ TELEFAX MESSAGE ◆◆◆◆

DATE:	December 23, 1997	# OF PAGES:	4
TO:	FDA <i>Wally</i>	FAX #:	301 594 4610
ATT:	<u>Harald</u> Pellerite Office of Compliance		
FROM:	Thomas K "Chip" Moore	SUBJECT:	Regulatory Compliance

Dear Mr. Pellerite,

Thank you for spending time with on the phone this morning. Enclosed with this fax are two examples of companies not in compliance with labeling requirements established by the FDA. Merss is a registered facility, however Midwest Medical is not. Neither have 510 (k)'s on file.

The obvious reason for my concern is customer confusion over terms used by the industry. In the cGMP, paragraph 820.3 Definitions, the remanufacturer clearly does more to a medical device than some one who simply refurbishes. Further, there should be the same enforcement of the regulation for every one.

We are, therefore, requesting that the above two mention companies label their products in accordance with current regulations. If I have misinterpreted the requirements, please advise.

Jim Schultz

Med Watch
Not similar to
med dev.

Sterilization Con
Greenwood Ind.

Steven Spencer
med/Dev lab
317 865 8950
866 625 4497

301
594
469.

FOA Chicago Dev
313-226-784

Jim Schultz

313 226 6260

EXT 151

Active Reg
301 495 7726



Getinge/Castle, Inc.
 1777 E. Henrietta Road
 Rochester, NY 14623-3133

Tel 716-272-5123
 Fax 716-272-5291

Exhibit I

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Thomas K. "Chip" Moore
 Senior Market Manager

**THIS DOCUMENT IS NOT INCLUDED BECAUSE IT
CONTAINS COPYRIGHTED MATERIALS**

**DOCKET
97N-0477 - C2**

ON

**MEDICAL DEVICES
REVIEW AND REVISION OF COMPLIANCE POLICY**

EXHIBIT 1

**HEALTH CARE PURCHASING NEWS - DECEMBER 1997
INFOMART: STERILIZERS, DECONTAMINATORS, AND ULTRASONIC EQUIPMENT**

THIS MATERIAL MAY BE OBTAINED BY:

VISITING THE PUBLIC ROOM AT:

**DOCKETS MANAGEMENT BRANCH
FOOD & DRUG ADMINISTRATION
12420 PARKLAWN DRIVE, ROOM 1-23
ROCKVILLE, MD 20857**

MODE = MEMORY TRANSMISSION START=JUL-16 12:23 END=JUL-16 12:24

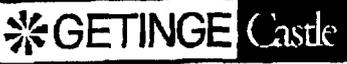
FILE NO. = 078

NO.	COM	ABBR/NTWK	STATION NAME/ TELEPHONE NO.	PAGES	PRG. NO.	PROGRAM NAME
001	OK		317183407057	002/002		

-MDT CASTLE CORP. -

***** -716 272 5291 - ***** 716 272 5291- *****

Exhibit II

	Getinge/Castle, Inc.	Tel 716-272-5123
	1777 E. Henrietta Road	Fax 716-272-5291
	Rochester, NY 14623-3133	

◆ ◆ ◆ ◆ TELEFAX MESSAGE ◆ ◆ ◆ ◆

DATE:	July 16, 1997	# OF PAGES:	2
TO:	FDA NY Office	FAX #:	718 340 7057
ATT:	Jerry Woysner		
FROM:	Thomas K "Chip" Moore	SUBJECT:	Regulatory Compliance

Dear Mr. Woysner,

Enclosed with this fax is an advertisement by Alfa Medical Equipment, INC, for a sterilizer, model Prestige 2100. The ad is from the July 1997 issue of Medical Equipment Publication. I have found the company listed in the 1996 Medical Register, no facility registration is available, nor can I find a 510(k) clearance to market this sterilizer. I further believe this sterilizer is an import.

On July 10, 1996, I wrote to Mr. E. Pitt Smith, previous FDA Director of the Buffalo office, about this company and four others who were advertising class II medical without proper clearance or compliance. Mr. Smith said he would forward the July 10th letter to your office for follow-up.

As a manufacture of sterilizers, we desire and seek fair and open competition. We further desire that medical device manufacture or distributors comply with regulatory requirements. Could you please follow-up with Alfa and determine compliance.

Regards

Thomas K. "Chip" Moore
Senior Market Manager

Exhibit II

◆ ◆ ◆ ◆ TELEFAX MESSAGE ◆ ◆ ◆ ◆

DATE:	July 16, 1997	# OF PAGES:	2
TO:	FDA NY Office	FAX #:	718 340 7057
ATT:	Jerry Woysner		
FROM:	Thomas K "Chip" Moore	SUBJECT:	Regulatory Compliance

Dear Mr. Woysner,

Enclosed with this fax is an advertisement by Alfa Medical Equipment, INC, for a sterilizer, model Prestige.2100. The ad is from the July 1997 issue of Medical Equipment Publication. I have found the company listed in the 1996 Medical Register, no facility registration is available, nor can I find a 510(k) clearance to market this sterilizer. I further believe this sterilizer is an import.

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Regards

Thomas K. "Chip" Moore
Senior Market Manager

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**DOCKET
97N-0477 - C2**

ON

**MEDICAL DEVICES
REVIEW AND REVISION OF COMPLIANCE POLICY**

EXHIBIT 2

**MEDICAL EQUIPMENT PUBLICATION
1265 INDUSTRIAL HIGHWAY
SOUTHAMPTON, PA 18966-4087**

THIS MATERIAL MAY BE OBTAINED BY:

VISITING THE PUBLIC ROOM AT:

**DOCKETS MANAGEMENT BRANCH
FOOD & DRUG ADMINISTRATION
12420 PARKLAWN DRIVE, ROOM 1-23
ROCKVILLE, MD 20857**

From the desk of

Chip Moore

Exhibit III

FDA LA

Ph 714 798 7600

Fx

~~715~~ 715

• Pro → 1

Henry Corea

9/25/97

Vicky Anderson

714 798 7701

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CONTAINS COPYRIGHTED MATERIALS**

**DOCKET
97N-0477 - C2**

ON

**MEDICAL DEVICES
REVIEW AND REVISION OF COMPLIANCE POLICY**

EXHIBIT 3

**MEDICAL EQUIPMENT PUBLICATION
1265 INDUSTRIAL HIGHWAY
SOUTHAMPTON, PA 18966-4087**

THIS MATERIAL MAY BE OBTAINED BY:

VISITING THE PUBLIC ROOM AT:

**DOCKETS MANAGEMENT BRANCH
FOOD & DRUG ADMINISTRATION
12420 PARKLAWN DRIVE, ROOM 1-23
ROCKVILLE, MD 20857**

Whit. TTT

Lancer Medical Services, Inc.

TEL: 1-626-969-0144 FAX: 1-626-969-4705

Welcome to our . . .

Customer Service Department

**Do you have some questions that you would like to ask?
Perhaps you need some spare parts for our products.
Would you like additional information?**

Please supply the following information, and indicate how you'd like us to respond.

Name:

Firm:

Phone:

Fax:

E-mail:

Address:

Response Method: Telephone Call
 E-Mail Message
 Surface Mail

Enter your text message below.

Send Request to Lancer Medical Systems

**Lancer Medical Services, Inc.
777 North Loren Avenue
Azusa, California 91702
U.S.A.**

**TEL: 1-626-969-0144
FAX: 1-626-969-4705**

LancerM@ix.netcom.com

[Return to Lancer Medical Systems Home Page](#)

GA 117 277

| [Explore the MedMart Network](#) | [Explore the MedStore Network](#) |

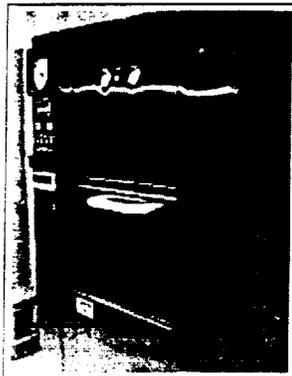
Lancer Medical Services, Inc.

We design, manufacture, sell and service general purpose sterilizers, surgical instrument washers, pharmaceutical grade GMP sterilizers, and biohazard waste retorts.

Our Product Spotlight



The Lancer Sterilizer



The Lancer GMP Compliant Pharmaceutical Grade Sterilizer

Contact Lancer Medical Services

Do you have questions or need additional information? Here is our Phone, FAX and E-mail Information.

Information About Who We Are

Learn about who we are, what we do - and what Lancer Medical Services' specialty is!

Passport Sterilizer

The Lancer Passport Sterilizer is a flash, or general purpose automatic sterilizer that is easy to operate, easy to maintain, inexpensive - and can tolerate adverse power line conditions.

Instrument Washer & Sanitizer

The Lancer Instrument Washer/Sanitizer is versatile, safe, efficient and economical! Don't handle contaminated surgical instruments until they have been sanitized - protect your techs!

Pharmaceutical Sterilizers

If your biotechnology or pharmaceutical applications requires a GMP compliant sterilizer - we've got it! Sizes available from 8 to 100 cubic feet.

Biological Waste Retort System

Tired of paying to have your red bags hauled away? Our Retort system will pay for itself in about six months. Don't be dependent on the disposal services!

Equipment We Are Seeking

We are always looking for specific types of equipment. Take a look at what our current needs are.



Counter initiated March 13, 1997

Lancer Medical Services, Inc.

TEL: 1-626-969-0144 FAX: 1-626-969-4705

About Our Company . . .

Welcome to Lancer Medical Services, and please do come in!

Lancer Medical Services is a full service company. We design, manufacture, stock, sell and service all that we offer. We are not a broker! Our plant is located in Azusa, California. Visitors are always welcome to come and check out our remanufacturing facilities and inventory.

Save 50% or more! Have you considered the benefits of equipping your facility with remanufactured or reconditioned equipment? Double your purchasing power without sacrificing quality or reliability.

Lancer Medical Services is famous for its Sterilizers - they're our specialty! Lancer Sterilizers are brand new units that have been built on remanufactured chambers. We utilize the very latest technology and only use very highest quality components. We can meet your sterilizer needs from our 16" Lancer Passport sterilizer, which is a general purpose Flash sterilizer, to the huge 60" Vacuum Sterilizer, with cart and carriage. We can build custom configurations to meet any need - just give our sales department a call, or contact us via e-mail.

Lancer Medical Services also remanufactures all models of the very popular AMSCO Eagle Sterilizer! We remanufacture these units to meet or exceed the original manufacturer's specifications - then make them available for resale at a fraction of what a new one would cost.

We've addressed the critical environmental issue with our new, self-contained Retort System! Sterilizers are not our only product. We remanufacture stainless steel operating tables too.

Lancer Medical Services guarantees parts on all remanufactured sterilizers for a period of 12 months. In Southern California the guarantee also includes labor. Our remanufactured sterilizer chambers are fully guaranteed for ten years - twice that of most new chambers!

[| Return to Lancer Medical Systems Home Page |](#)

[| Explore the MedMart Network |](#) [| Explore the MedStore Network |](#)

Exhibit 10

July 10, 1996

Mr. E. Pitt Smith
Director, Buffalo District
Food & Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

Dear Mr. Smith:

Ms. Sherry Phillips of the Food & Drug Administration's Rochester office suggested I write to you to express our concerns regarding the sale of refurbished or remanufactured sterilizers. As you are probably aware, MDT Corporation manufactures medical devices and at our Henrietta facility, we manufacture sterilizers with the brand name Castle®.

In reviewing 21 CFR-Part 820, paragraph 820.115 establishes requirements for reprocessing of devices. With the recent cost restraints placed on healthcare facilities, a number of companies have begun to offer reconditioned, refurbished or remanufactured medical devices. Enclosed with this letter are five examples of companies offering sterilizers for sale. I have found some of them listed in the *Medical Device Register*®, none appeared to be a registered medical device facility.

It is my understanding that to offer remanufactured medical devices, like sterilizers, the manufacturer must be a registered facility and have FDA clearance to market such products through the 510(k) process. I have confirmed this with Mr. Wes Morganstern (301/594-4699) of the FDA Compliance Office. He further said that if the medical device were to be reconditioned to the original manufactured specification, then a 510(k) clearance would not be necessary. I believe a registered facility is required in any case.

The purpose of this letter is to ask for a competitive environment in the sale of sterilizers. The companies that have advertised in the *Medical Equipment* magazine (215/355-2886) should be in regulatory compliance as the original manufacturers. If you would like to call me for further discussions, you can reach me at (716) 272-5123. Thank you for your consideration in this matter.

Sincerely,

Thomas K. "Chip" Moore
Senior Market Manager

TKM:dbb
Enclosures

cc: M. Hilkert (w/ Enclosures)
R. Von Kaenel "

Edwin. 11V

MEDICAL EQUIPMENT
Volume 6, Issue 6
June 1996

<u>Page #</u>	<u>Advertiser</u>
29	Alfa Medical 59 Madison Avenue Hempstead, NY 11550 (516) 773-4339
34	GVS-NY 2099 New Highway Farmingdale, NY 11735 (516) 753-2100
36	EBCO Scientific 215 N. Village Terrace P.O. Box 492 Tonganoxie, KS 66086 (913) 845-3232
56	Sterile Technologies, Inc. 240C Queensbury Avenue Queensbury, NY 12804 (518) 793-7077
63	Midwest Medical Equipment, Inc. 9117 W. Belden Avenue Franklin Park, IL 60131 (847) 288-9900



Technology for Life

Exhibit V *C. Moore*
Sales Bulletin

MDT Corporation

Subject: Standards for Sterilizers

Date: September 16, 1996

Distribution: Healthcare Sales
International Sales
Canadian Sales
Service Division

No: 55-96

Attached is a letter that you can use to help educate your customers on some of the requirements for the manufacture of either new sterilizers or remanufactured.

Our business is regulated and compliance is a legal requirement. Often, price is the prime purchase determinant, when the informed purchaser should be thinking about the safety, efficacy, service and quality of the sterilizer.

Help your customers understand, then they will be assured of receiving full value for their capital investments. If you would like additional copies of this standards letter, order form number 135-2090 from the print shop.

Thomas K. "Chip" Moore
Senior Market Manager

Attachment



Technology for Life

Exhibit V

MDT Biologic Company

1777 East Henrietta Road (14623) P.O. Box 23077 Rochester, New York 14692-3077 U.S.A. Telephone (716) 475-1400 Facsimile (716) 272-5033

September 1996

Dear Healthcare Consumer:

Your institution may have product evaluation procedures in place for purchasing new equipment from medical device manufacturers. These procedures may include certain requirements, such as electrical safety, compliance with local plumbing codes, delivery and after sale service capabilities to name just a few. Given tight financial conditions these days, it's even more important that you receive full value for the capital invested in equipment whether you're purchasing new or remanufactured medical devices. It's especially true if you're purchasing a sterilizer, because the patient deserves a sterile product, every time.

Now that Getinge has acquired MDT Corporation, we are the leading sterilizer and disinfectant manufacturer in the world. Domestically, you are familiar with the 113-year-old brand name Castle® – a name that is synonymous with quality and reliability. You may not know that we now offer a line of remanufactured sterilizers. The intent of this communication is to help you expand your purchasing procedures to define additional requirements to insure you receive maximum value for your capital expenditure. By incorporating the following into your prebid requirements, you can avoid complications when the sterilizer arrives on site.

Regulated Industry

The Food and Drug Administration (FDA) regulates the medical device industry. Sterilizers, used in healthcare facilities to process packs and instruments for patient care use, are considered class II medical devices. The following is merely a brief outline of some of the requirements for new or remanufactured medical devices.

- Current Good Manufacturing Practices (cGMP).
 - Defined in 21 CFR - Part 820.
 - Requires facility registration.
- Requires clearance to market, either the Pre-Market Approval or the 510(k) submittal process. The reference is 21 CFR - Part 807.

Additionally, the Safe Medical Device Act requires filing of a Medical Device Report if a serious injury or death is caused by a medical device. Being a registered facility makes it easier for the FDA to locate the manufacturer.

At bid preparation time, it would be to your advantage to request the facility registration number and 510(k) number to substantiate regulatory compliance.



Technology for Life

Exhibit V

Healthcare Consumer
Page 2
September 1996

The following definitions are provided to help you differentiate what is offered:

1. **REMANUFACTURED:** The sterilizer is stripped down to the chamber and closure, sandblasted and painted. Current production controls, frame support and piping are configured just as a new one. Once assembled, it would be hard to tell the difference from a new one.
2. **USED:** Sold as is from one location to another without repairs or updating. Product is to the original manufacturer's specifications.
3. **REFURBISHED:** Worn out parts are replaced, product is to the original manufacturer's specifications.

Electrical Safety

Many biomedical departments require that medical devices be listed by certified testing facilities to insure that they are safe to use. Our industry recognizes the UL 544 Electrical Code for Medical Devices. Sterilizer manufacturers use nationally recognized testing labs, such as ETL Testing Lab, to certify the design and components to the UL 544 standard. Once approval is received, the models reviewed can be labeled with the ETL certification. Each and every sterilizer manufactured is built to this standard. Remanufactured sterilizers also comply with the ETL certification, if they are remanufactured by the original equipment manufacturer. This means the sterilizer will pass electrical code inspection if installed during renovation or construction. It's to your advantage to require UL 544 certification in your bid request.

Measuring Sterilization Performance

Having FDA clearance to market a sterilizer means the company has at least completed efficacy testing to Association for the Advancement of Medical Instrumentation (AAMI) standards. The size of the piping and solenoids, steam flow rates, vacuum depths, are just some of the critical areas that affect whether a sterilizer performs or not. The manufacturer sterilization tests are found in the AAMI document ST 8, known as "Hospital Steam Sterilizer," which is an American National Standard. There are AAMI standards for users like you and these documents provide tests to biologically challenge sterilizers located in a central supply department or the operating room. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) reviews your infection control procedures to verify that you are following the stated guidelines. Ultimately, the patient benefits when the sterilizer is manufactured to a performance standard and your healthcare facility follows the current standards for sterility assurance. It's to your benefit to require proof that the sterilizer, either new or



Technology for Life

Exhibit V

Healthcare Consumer

Page 3

September 1996

remanufactured, meets established manufacturer performance standards such as AAMI ST 8.

Standards of Quality

In the definition above, used, refurbished and remanufactured sterilizers were discussed. We thought it might be helpful to itemize the steps that we go through in the production of remanufactured sterilizers. When compared to what you might get when a decision is made for a used or refurbished sterilizer, remanufactured sterilizers are built to a quality standard, every time.

1. Used sterilizers are shipped to our Rochester, New York, facility, where they are received and inspected. The material thickness of the chamber walls is checked electronically. Chambers that do not meet the minimum requirements, are rejected.
2. All piping, electrical components and support frames are removed and the chambers and closures are sandblasted, cleaning the chambers to a like new condition. Exterior metal is painted with a corrosion-resistant paint to prevent rusting. Any welding repairs are made.
3. After a hydro test which verifies the chamber integrity by stressing the chamber to one and a half times its maximum allowable working pressures, a new remanufactured plate is affixed to the chamber adjacent to the ASME plate. Any welding repairs requires this for National Board registration, an important item for your insurance carrier and local boiler inspector.
4. During assembly, a new production support frame, piping and controls are installed and tested. If an electric steam generator integral to the sterilizer is required, a new boiler is installed to the electrical characteristic specified. ETL labels are attached to certify electrical safety compliance. New operators manuals are included with every shipment.
5. The net result is that the sterilizer you receive looks like a new one, has ETL certification and meets AAMI performance standards. Installation checkout is performed by one of our factory-trained service representatives and backed by our first year warranty. Preventative maintenance agreements are available to help keep your sterilizer performing up to manufacturing specifications, year after year.

We sincerely hope that this communication helps you establish purchasing requirements that will insure certain standards are met. We want you to be a satisfied



Technology for Life

Exhibit V

Healthcare Consumer
Page 4
September 1996

customer, and the best way to achieve that goal is to know what you're buying. You may be familiar with the old sayings, "all that glitters is not gold" and "you get what you pay for." Sterilizers are medical devices that perform a critical function every day for your patients. Know what you're buying.

If you should have any questions on the above subject or any sterilization question, call me at (716) 272-5123, and I'll do my best to help you.

Thank you for your interest in Castle Sterilizers.

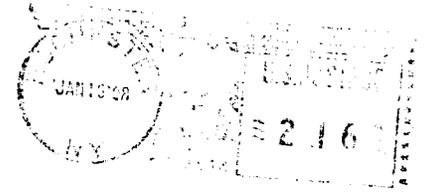
Sincerely,

A handwritten signature in cursive script that reads "Chip Moore".

Thomas K. "Chip" Moore
Senior Market Manager



Getinge/Castle, Inc.
1777 East Henrietta Road
Rochester, NY 14623-3133



First Class Mail

Dockets MANAGEMENT Branch (HFA-305)
Food and Drug Administration
12420 ParkLawn Dr
Room 1-23
Rockville, MD 20857