DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1528]

Delfina Hernandez; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) debarring Ms. Delfina Hernandez for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Hernandez was convicted of a felony under Federal law for conspiring to make false statements in matters within the jurisdiction of a government agency, and that Ms. Hernandez' conduct undermined the process for the regulation of drugs. Ms. Hernandez has failed to request a hearing and, therefore, has waived her opportunity for a hearing concerning this action.

DATES: This order is effective November 6, 2002.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On October 22, 1997, the U.S. District Court for the Central District of California accepted Ms. Hernandez' plea of guilty to one count of conspiring to make false statements in matters within the jurisdiction of a government agency, FDA, a Federal felony offense under 18 U.S.C. sections 371 and 1001. This conviction was based on Ms. Hernandez' participation in falsifying data and information on clinical studies for use by FDA in determining the safety and effectiveness of drug products.

As a result of this conviction, FDA served Ms. Hernandez by certified mail on May 13, 2002, a notice proposing to debar her for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Ms. Hernandez an opportunity for a hearing on the proposal. The debarment proposal was based on a finding, under section 306(b)(2)(B)(i)(II) and (a)(2) of the act (21 U.S.C. 335a(b)(2)(B)(i)(II) and (a)(2)) that Ms. Hernandez was convicted of a felony under Federal law for conspiring to make false statements in matters within the jurisdiction of a government agency, FDA, and that Ms. Hernandez' conduct undermined the process for the regulation of drugs. Ms. Hernandez was provided 30 days to file objections and to request a hearing. Ms. Hernandez did not request a hearing. Her failure to request a hearing constitutes a waiver of her opportunity for a hearing and a waiver of any contentions concerning her debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(b)(2) of the act, and under authority delegated to her (21 CFR 5.99), finds that Ms. Delfina Hernandez has been convicted of conspiracy to commit a felony under Federal law for conduct relating to the regulation of drug products and that Ms. Hernandez' conduct undermined the process for the regulation of drugs.

As a result of the foregoing finding, Ms. Delfina Hernandez is debarred for 5 years from providing services in any capacity to a person that has an approved or pending drug product application under section 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (see sections 306(c)(1)(B) and (c)(2)(A)(iii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Ms. Hernandez, in any capacity during her period of debarment, will be subject to civil money penalties. If Ms. Hernandez, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Ms. Hernandez during her period of debarment.

Any application by Ms. Hernandez for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 00N–1528 and sent to the Dockets Management Branch (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 15, 2002.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 02–28255 Filed 11–5–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 02M–0250, 02M–0203, 02M–0180, 02M–0218, 02M–0272, 02M–0271, 02M–0145, 02M–0311, 02M–0172, 02M–0217, 02M–0179, 02M–0255, 02M–0173, 02M–0235, 02M–0167, 02M–0174, 02M–0216, and 02M–0236]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In January 1998, FDA revised 21 CFR 814.44(d) and 814.45(d) (63 FR 4571, January 30, 1998) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information to FDA's home page at

http://www.fda.gov on the Internet. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure described above from April 1, 2002, through June 30, 2002. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE APRIL 1, 2002, THROUGH JUNE 30, 2002

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P000008/02M–0250	BioEntrics Corp.	LAP–BAND Adjustable Gastric Banding System	June 5, 2001.
P980033/02M–0203	Boston Scientific Scimed, Inc.	WALLSTENT Endoprosthesis	November 16, 2001.
P010027/02M–0180	Ophthalmic Innovations International, Inc.	ALLERGAN, INC. Model AC 21B Anterior Chamber Intraocular Lens (Cataract)	November 21, 2001.
P010033/02M–0218	Cellestis Ltd.	QUANTIFERON–TB	November 28, 2001.
P000049/02M–0272	Nitinol Medical Technologies, Inc.	CARDIOSEAL Septal Occlusion System With QWIKLOAD	December 5, 2001.
P000039/02M–0271	AGA Medical Corp.	THE AMPLATZER Septal Occluder (ASO) And AMPLATZER Exchange System	December 5, 2001.
P010030/02M–0145	Lifecor, Inc.	Wearable Cardioverter Defibrillator (WCD) 2000 ''Lifevest'' System	December 18, 2001.
H000002/02M–0311	VISX, Inc.	VISX EXCIMER LASER SYSTEM AND CUSTOM CONTOURED ABLATION PATTERN (C0–CAP) METHOD	December 19, 2001.
P980024(S1)/02M–0172	Vysis	PATHVYSION HER–2 DNA Probe Kit	December 31, 2001.
P9600009(S7)/02M–0217	Medtronic, Inc.	MEDTRONIC ACTIVA Parkinson's Control System	January 14, 2002.
P010054/02M–0179	Roche Diagnostics Co.	ELECSYS ANTI–HBS Immunoassay PRECICONTROL ANTI02M–HBS	February 28, 2002.
P000037(S1)/02M–0255	Medical Carbon Research Institute, LLC	ON–X Prosthetic Heart Valve, Models ONXM and ONXMC	March 6, 2002.
P010025/02M–0173	Hologic, Inc.	LORAD Digital Breast Imager	March 15, 2002.
P000033/02M–0235	SulzerIntra Therapeutics, Inc.	INTRACOIL Self-Expanding Peripheral Stent	April 3, 2002.
H000007/02M–0167	AGA Medical Corp.	AMPLATZER PFO Occluder	April 5, 2002.
P010018/02M–0174	Refractec, Inc.	VIEWPOINT CK SYSTEM	April 11, 2002.
P900033(S8)/02M–0216	Integra Lifesciences, Corp.	INTEGRA Dermal Regeneration Template	April 19, 2002.
P010012/02M–0236	Guidant Corp.	CONTAK CD/EASYTRAK Lead System, Models 4510, 4511, 4512, And 4513	May 2, 2002.

II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/cdrh/pmapage.html.

Dated: October 23, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–28155 Filed 11–5–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0449]

''Draft Guidance for Industry: The Administrative New Animal Drug Application Process''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#132) entitled ''The Administrative New Animal Drug Application Process.'' The guidance defines what an administrative new animal drug application (NADA) is, the procedures that should be followed before a sponsor submits an administrative NADA, and the intended timeframe for review of administrative NADAs.

DATES: Submit written or electronic comments on the draft guidance by January 21, 2003, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

Submit written comments on the information collection requirements by January 6, 2003.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http:///www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the draft guidance document and the docket number found in the heading of this document.

Submit written comments on the collection of information requirements to the Dockets Management Branch (address above). Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Gail Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1796, e-mail: gschmer1@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*) prohibits the introduction into interstate commerce of new animal drugs that are not the subject of an approved NADA. Section 512(b) of the act (21 U.S.C. 360b) and part 514 (21 CFR part 514) describe the information that must be submitted to FDA, specifically CVM, as part of an NADA. CVM encourages sponsors to submit data for review at the most appropriate and productive times in the drug development process. Sponsors may submit, and CVM intends to review, data in support of discrete technical sections during the investigation of the new animal drug. The guidance explains phased review and direct review, describes the technical sections, tells sponsors how they should submit data or information in support of a technical section for review, and tells sponsors how they should submit an administrative NADA.

An administrative NADA is an NADA that is submitted after CVM has reviewed all of the technical sections containing the information required for the approval of the new animal drug and CVM has issued a technical section complete letter for each of those technical sections.

II. Significance of Guidance

The level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking about the administrative NADA process. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

III. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: The Administrative New Animal Drug Application Process.

Description: The act prohibits the introduction into interstate commerce of new animal drugs that are not the subject of an approved NADA. Section 512(b) of the act and the regulations in part 514 describe the information that must be submitted to FDA, specifically to CVM, as part of an NADA.

CVM encourages sponsors to submit data and information for review at the most appropriate and productive times in the drug development process rather than submitting all data and information at one time. Sponsors may submit, and CVM intends to review, data or information in support of discrete technical sections during the investigation of the new animal drug. This process is known as phased review. Sponsors may submit part or all of the data and information needed to support a technical section in a phased submission. The data submitted in