Agency's current thinking on meetings with OOPD. 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 approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB control numbers 0910–0167, 0910–0332, and 0910–0787.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or at *http://www.regulations.gov.*

Dated: July 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16773 Filed 7–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2100]

Patricia Durr: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Patricia Durr 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. Durr was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Ms. Durr was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Ms. Durr failed to request a hearing. Ms. Durr's failure to request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective July 9, 2015.

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

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr. (ELEM–4144), Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act.

On April 2, 2014, the U.S. District Court for the Eastern District of Virginia entered judgment against Ms. Durr for one count of introducing misbranded drugs into interstate commerce with intent to defraud or mislead, in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a) and 333(a)(2)).

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: Ms. Durr was a sales representative for Gallant Pharma International Inc. (Gallant Pharma) between October 2010 and August 2013, and was responsible for selling injectable cosmetic drugs and devices, and intravenous chemotherapy drugs, to doctors and hospitals in Massachusetts and Connecticut. Some of the drugs Ms. Durr facilitated the sale of were misbranded within the meaning of the FD&C Act.

Ms. Durr admitted that she sold drugs which were not approved by the FDA for use on patients in the United States. She further admitted that the drugs she sold on behalf of Gallant Pharma were misbranded in that they did not bear adequate directions for use and were not subject to an exemption from that requirement, and they were accompanied by non-FDA approved packaging and inserts.

Between August 2012 and August 2013, Ms. Durr admitted to selling more than $699,000 in misbranded drugs and devices to doctors and medical practices in Massachusetts and Connecticut. She further admitted that the loss amount attributable to her personal sales, under U.S. Sentencing Guidelines, was between $400,000 and $1,000,000.

Between October 2010 and August 2013, Ms. Durr personally sold misbranded drugs to 33 distinct doctors and medical practices, and generated more than $2.6 million in illegal proceeds from these sales. She admitted that, as of August 2012, she became willfully blind to the illegality of Gallant Pharma's business. Nonetheless, she continued her sales activity with Gallant Pharma until her arrest in August 2013.

As a result of her conviction, on March 9, 2015, FDA sent Ms. Durr a notice by certified mail proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on the finding, under section 306(a)(2)(B) of the FD&C Act, that Ms. Durr was convicted of a felony under Federal law for conduct related to the regulation of a drug product. FDA determined that Ms. Durr's felony conviction was related to the regulation of drug products because the conduct underlying her conviction undermined FDA's regulatory oversight over drug products marketed in the United States by intentionally introducing into interstate commerce drug products that did not bear adequate directions for use and were not subject to an exemption from that requirement, and which, among other things, were accompanied by non-FDA approved packaging and inserts. The proposal also offered Ms. Durr an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on March 24, 2015. Ms. Durr failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and has waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Patricia Durr has been convicted of a felony under federal law for conduct relating to the regulation of a drug product. Section 306(c)(2)(A)(ii) of the FD&C Act (21 U.S.C. 335a(c)(2)(A)(ii)) requires that Ms. Durr's debarment be permanent.

As a result of the foregoing findings, Patricia Durr is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see DATES) (see section 201(dd), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act (21 U.S.C. 321(dd), 335a(c)(1)(B), and 335a(c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Patricia Durr, in any capacity during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Durr provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Patricia Durr during her period of debarment (section 306(c)(1)(A) of the FD&C Act (21 U.S.C. 335a(c)(1)(A))).

Any application by Ms. Durr for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA–2014–N–2100 and sent to the Division of Dockets Management (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.

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 25, 2015.

Douglas Stearn,

Director, Division of Compliance Policy, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2015–16665 Filed 7–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2167]

Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing.'' This draft guidance describes FDA's intent to address the safety concerns by clarifying new expectations for labeling with regard to the soon-to-be revised heparin United States Pharmacopeia (USP) monographs as well as outline safety testing recommendations. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 7, 2015.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies of the draft guidance document entitled ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Angela Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1666, Silver Spring, MD 20993–0002, 301–796–6380.

SUPPLEMENTARY INFORMATION:

I. Background

The USP [1] heparin monographs have recently undergone several revisions following serious and fatal events related to the use of heparin sodium products. Investigation of heparin product overdose errors identified the expression of drug strength in the labels as a major contributing factor in these errors. This draft guidance document is intended to address these safety concerns by clarifying new expectations for labeling with regard to the soon-to-be revised heparin USP monographs (USP36–NF31),[2] as well as outline safety testing recommendations.

In addition, the outbreak of serious and often fatal events due to heparin contamination with over-sulfated chondroitin sulfate in 2008 led the USP to include in its monograph additional testing of heparin source material to ensure its quality and purity. This draft guidance also outlines use of conformance to the monograph in premarket submissions, specifically testing and documentation requirements and recommendations contained in the current USP monograph, and the guidance document ''Heparin for Drug and Medical Device Use: Monitoring Crude Heparin for Quality'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatory*

[1] USP is a scientific nonprofit organization that develops standards for the identity, strength, quality, and purity of drugs and drug ingredients marketed in the United States. These standards are published in USP's official compendia, ''United States Pharmacopeia and National Formulary.''

[2] USP monograph, USP PF 38 (3) and (5) Interim Revision Announcement, with proposed effective revision date of May 1, 2013. See also ''FDA Drug Safety Communication: Important Change to Heparin Container Labels to Clearly State the Total Drug Strength'' at *http://www.fda.gov/Drugs/DrugSafety/ucm330695.htm.*