ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General Population of Internet Users ..... Eligible participants, ages 18 and older in the U.S.	Screening and Consent Questionnaire	50,000	1	2/60
	Digital Media and Tobacco Outcomes Questionnaire (Wave 1).	5,000	1	20/60
	Digital Media and Tobacco Outcomes Questionnaire (Wave 2).	2,400	1	20/60
				Total

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–16772 Filed 7–8–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0313]

Meetings With the Office of Orphan Products Development; Guidance for Industry, Researchers, Patient Groups, 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 a guidance for industry, researchers, patient groups, and FDA staff entitled ''Meetings with the Office of Orphan Products Development.'' This guidance provides recommendations to industry, researchers, patient groups, and other stakeholders (collectively referred to as ''stakeholders'') interested in requesting a meeting with FDA's Office of Orphan Products Development (OOPD) on issues related to orphan drug designation requests, humanitarian use device (HUD) designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related topics of concern. This guidance document is intended to assist these groups with requesting, preparing, scheduling, conducting, and documenting meetings with OOPD. This guidance finalizes the draft guidance of the same title dated April 2014.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Orphan Products Development (OOPD), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5295, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling OOPD at 301–796–8660. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: James D. Bona, Office of Orphan Products Development (OOPD), Food and Drug Administration, Bldg. 32, Rm. 5204, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8673, email: *james.bona@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry, researchers, patient groups, and FDA staff entitled ''Meetings with the Office of Orphan Products Development.'' Each year, OOPD staff participates in meetings with stakeholders who seek guidance or clarification relating to orphan drug or HUD designation requests, OOPD grant programs, or other rare disease issues. These meetings can be ''informal'' or ''formal'' and help build a common understanding on FDA's thoughts on orphan products, which may include drugs, biological products, devices, or medical foods for a rare disease or condition. These meetings may represent critical points in the orphan product development process and may even have an impact on the eventual availability of products for patients with rare diseases and conditions. It is important that these meetings be scheduled within a reasonable time, conducted effectively, and documented where appropriate. This guidance is intended to provide consistent procedures to promote well-managed meetings between OOPD and stakeholders.

Topics addressed in this guidance include: (1) Clarification of what constitutes an ''informal'' or ''formal'' meeting, (2) program areas within OOPD that may be affected by this draft guidance, (3) procedures for requesting and scheduling meetings with OOPD, (4) description of what constitutes a meeting package, and (5) procedures for the conduct and documentation of meetings with OOPD.

In the **Federal Register** of April 9, 2014 (79 FR 19623), FDA issued, for public comment, ''Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings with the Office of Orphan Products Development.'' The Agency issued this draft guidance to assist stakeholders with requesting, preparing, scheduling, conducting, and documenting meetings with OOPD. In particular, the draft guidance provided clarification on what constitutes an ''informal'' or ''formal'' meeting, program areas within OOPD that may be affected by the guidance, procedures for requesting and scheduling meetings with OOPD, description of what constitutes a meeting package, and procedures for the conduct and documentation of meetings.

We received several comments on the draft guidance. Most comments appreciated the clarification and explanation provided by the draft guidance. Some comments made recommendations to improve clarity.

FDA is issuing the draft guidance in final form with minor revisions to improve clarity. This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the

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).