TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
315.4, 315.5, and 315.6	2	1	2	2,000	4,000
Total					4,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 30, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25685 Filed 10–4–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0165]

Deborah Martinez Seldon: 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 FD&C Act) permanently debarring Deborah Martinez Seldon 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. Seldon was convicted of multiple felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Ms. Seldon was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Ms. Seldon failed to respond. Ms. Seldon's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective October 5, 2011.

ADDRESSES: Submit applications for special 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 Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, 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 March 27, 2009, judgment was entered against Ms. Seldon in the United States District Court for the District of Nevada for mail fraud, in violation of 18 U.S.C. 1341, aiding and abetting, in violation of 18 U.S.C. 2, and misbranding a drug while held for sale, in violation of 21 U.S.C. 331(k) and 333(a)(2).

The FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the regulation of a drug product. The factual basis for those convictions is as follows: Ms. Seldon was the manager of her husband's medical practice called A New You Medical Aesthetics (A New You) in Las Vegas, Nevada. As the office manager of A New You, Ms. Seldon was responsible for ordering supplies, paying bills, managing personnel, and managing the bank accounts.

From, on or about, October 15, 2003, until on or about September 16, 2005, in the State and Federal District of Nevada, Ms. Seldon and her husband, aided and abetted by each other, devised a scheme and artifice to fraudulently obtain money from patients by substituting the cheaper, non-FDA approved product marketed by Toxin Research International that purported to be Botulinum Neurotoxin Type A (TRI-toxin) in treatments provided to patients at A New You, while falsely and fraudulently representing to the patients that they were receiving injections of the FDA-approved BOTOX product marketed by Allergan, Inc..

As part of the scheme Ms. Seldon ordered and caused to be ordered 38 vials of TRI-toxin between October 2003 and September 2004 while at the same time the practice stopped purchasing the approved BOTOX in October 2003. In January 2005, as part of the scheme and artifice, Ms. Seldon arranged for a secret purchase of, and received 132 vials of TRI-toxin for use at A New You.

Ms. Seldon and her husband defrauded patients by misleading them to believe that they were receiving the FDA-approved drug BOTOX, when, in fact, the patients were receiving TRI-toxin, which was not approved, thereby exposing patients to severe health risk. On or about January 12, 2005, Ms. Seldon caused to be falsified computerized medical records by deleting references to BOTOX and changing these entries to the generic notation ''Cosmetic Procedure.'' In furtherance of their scheme, Ms. Seldon and Dr. Seldon caused 28 vials of TRI-toxin to be returned to the FDA, seeking to create the misleading impression that they were returning 28 of the original 38 vials they had purchased. In fact, all of the original TRI-toxin had been used on patients at A New You, and Ms. Seldon was returning vials that were part of the secret 132 vial purchase.

Ms. Seldon and her husband also caused advertisements to be placed in local magazines offering BOTOX, creating the false impression that the office was using approved BOTOX when, in fact, patients were being injected with unapproved TRI-toxin. Ms. Seldon also caused patients to sign consent forms that fraudulently represented that Dr. Seldon would be injecting approved BOTOX when she knew her husband was injecting them with TRI-toxin.

As a result of her convictions, on May 23, 2011, FDA sent Ms. Seldon 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 a finding, under section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)), that Ms. Seldon was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Ms. Seldon 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. Ms. Seldon received the proposal on May 27, 2011, and failed to respond within the timeframe prescribed by regulation. She therefore has waived her opportunity for a hearing and any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)), under authority delegated to him (Staff Manual Guide 1410.35), finds that Deborah Martinez Seldon has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Ms. Seldon 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 306(c)(1)(B), (c)(2)(A)(ii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(ii), and 321(dd))). 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 Ms. Seldon in any capacity during Ms. Seldon's 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. Seldon 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 Deborah Martinez Seldon 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 Deborah Martinez Seldon 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–2011–N–0165 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(j).

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

Dated: September 6, 2011.

Armando Zamora,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2011–25680 Filed 10–4–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 1, 2011, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You'', click on ''Public Meetings at the FDA White Oak Campus''. Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, *Fax:* 301–847–8533, *e-mail: ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On November 1, 2011, information will be presented regarding pediatric development plans for four products that were either recently approved by FDA, are in late stage development for an adult oncology indication, or in late stage development in pediatric patients with cancer. The subcommittee will consider and discuss issues relating to the development of each product for pediatric use and provide guidance to facilitate the formulation of Written Requests for pediatric studies, if appropriate. The four products under consideration are: (1) Sodium thiosulfate injection, application submitted by Adherex Technologies, Inc.; (2) vismodegib (GDC–0449), application submitted by Genentech, Inc.; (3) pazopanib, application submitted by Glaxo Wellcome Manufacturing Pte Ltd., Singapore doing business as GlaxoSmithKline; and (4) Medi-573 (fully human antibody to IGF–I and IGF–II), application submitted by MedImmune, LLC.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 18, 2011. Oral presentations from the public will be scheduled between approximately 9:15 a.m. to 9:30 a.m., 11:15 a.m. to 11:30 a.m., 2:05 p.m. to 2:20 p.m., and 4:10 p.m. to 4:25 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed