Dated: September 30, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–25686 Filed 10–4–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0405]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 4, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0409. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring—21 CFR Part 315 (OMB Control Number 0910–0409)—Extension

FDA is requesting OMB approval of the information collection requirements contained in 21 CFR 315.4, 315.5, and 315.6. These regulations require manufacturers of diagnostic radiopharmaceuticals to submit information that demonstrates the safety and effectiveness of a new diagnostic radiopharmaceutical or of a new indication for use of an approved diagnostic radiopharmaceutical.

In response to the requirements of section 122 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), FDA published a final rule in the **Federal Register** of May 17, 1999 (64 FR 26657), amending its regulations by adding provisions that clarify the Agency's evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis or monitoring of diseases. The regulation describes the kinds of indications of diagnostic radiopharmaceuticals and some of the criteria that the Agency would use to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) (the FD&C Act) and section 351 of the Public Health Service Act (42 U.S.C. 262) (the PHS Act). Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables FDA to properly evaluate the safety and effectiveness profiles of a new diagnostic radiopharmaceutical or a new indication for use of an approved diagnostic radiopharmaceutical.

The rule clarifies existing FDA requirements for approval and evaluation of drug and biological products already in place under the authorities of the FD&C Act and the PHS Act. The information, which is usually submitted as part of a new drug application or biologics license application or as a supplement to an approved application, typically includes, but is not limited to, nonclinical and clinical data on the pharmacology, toxicology, adverse events, radiation safety assessments, and chemistry, manufacturing, and controls. The content and format of an application for approval of a new drug are set forth in § 314.50 (21 CFR 314.50). Under 21 CFR part 315, information required under the FD&C Act and needed by FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals still needs to be reported.

Based on the number of submissions (that is, human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals) that FDA receives, the Agency estimates that it will receive approximately two submissions annually from two applicants. The hours per response refers to the estimated number of hours that an applicant would spend preparing the information required by the regulations. Based on FDA's experience, the Agency estimates the time needed to prepare a complete application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulation does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours because safety and effectiveness information is already required by § 314.50 (collection of information approved by OMB under OMB control number 0910–0001). In fact, clarification in these regulations of FDA's standards for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies. Table 1 of this document contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by existing regulations. This estimate does not include the actual time needed to conduct studies and trials or other research from which the reported information is obtained.

In the **Federal Register** of June 10, 2011 (76 FR 34079), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

FDA estimates the burden of this collection of information as follows:

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]

BILLING CODE 4160–01–P

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