DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0629]

Stephen Lee 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 Stephen Lee Seldon, M.D. from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Dr. Seldon was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Seldon was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Seldon failed to respond. Dr. Seldon's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective May 27, 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, Office of Regulatory Affairs (HFC–230), 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, the U.S. District Court for the District of Nevada entered judgment against Dr. Seldon for mail fraud in violation of 18 U.S.C. 1341, aiding and abetting, in violation of 18 U.S.C. 2, and misbranded a drug while held for sale in violation of 21 U.S.C. 331(k) and 333(a)(2).

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: Dr. Seldon was a physician licensed by the State of Nevada to practice medicine. He owned and operated a practice called A New You Medical Aesthetics (A New You) in Las Vegas, Nevada. From on or about October 15, 2003, until on or about September 16, 2005, in the State and Federal District of Nevada, and elsewhere Dr. Seldon and his wife, aided and abetted by each other, devised a scheme and artifice to fraudulently obtain money from patients by substituting cheaper, non-FDA approved product marketed by Toxin Research International, Inc. (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 more expensive, FDA-approved BOTOX product manufactured by Allergan, Inc.

As part of the scheme, Dr. Seldon ordered and caused to be ordered 38 vials of TRI-toxin between October 2003 and September 2004 while at the same time his practice stopped purchasing the approved BOTOX.

As part of his scheme, Dr. Seldon spoke at a seminar in Scottsdale, Arizona, in September 2004, sponsored by Toxin Research International, Inc. and claimed that he used it on patients in his practice, notwithstanding a warning on each vial that TRI-toxin was for research purposes only and not for human use.

Dr. Seldon defrauded his 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 FDA-approved, thereby exposing the patients to severe health risk. Dr. Seldon also caused advertisements to be placed in local magazines offering BOTOX injections, creating the false impression that he was using the FDA-approved BOTOX. Dr. Seldon additionally caused patients to sign consent forms that fraudulently represented that he would be injecting approved BOTOX when he knew he would be injecting the patients with TRI-toxin.

As a result of his convictions, on February 22, 2011, FDA sent Dr. Seldon a notice by certified mail proposing to permanently debar him 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, that Dr. 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 Dr. Seldon an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him 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 February 25, 2011. Dr. Seldon failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his 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, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Stephen Lee 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, Dr. 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 sections 306(c)(1)(B), (c)(2)(A)(ii), and 201(dd) of the FD&C Act (21 U.S.C. 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 Dr. Seldon, in any capacity during Dr. 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 Dr. Seldon provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he 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 Dr. Seldon during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Seldon for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2010–N–0629 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: May 16, 2011.

Howard Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2011–13198 Filed 5–26–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Health Education Assistance Loan (HEAL) Program: Lender's Application for Insurance Claim Form and Request for Collection Assistance Form (OMB No. 0915–0036)—Extension

The clearance request is for an extension of two forms that are currently approved by OMB. HEAL Lenders use the Lenders Application for Insurance Claim to request payment from the Federal Government for federally insured loans lost due to borrowers' death, disability, bankruptcy, or default. The Request for Collection Assistance form issued by HEAL lenders to request federal assistance with the collection of delinquent payments from HEAL borrowers.

The annual estimate of burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Lender's Application for Insurance Claim Form 510	17	25	425	0.5	213
Request for Collection Assistance Form 513	17	550	9,350	0.167	1,561
Total	34				1,774

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 23, 2011.

Jennifer L. Riggle,

Deputy Director, Office of Management.

[FR Doc. 2011–13206 Filed 5–26–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Reconciliation Tool for the Teaching Health Center Graduate Medical Education Program—[NEW]

The Teaching Health Center Graduate Medical Education (THCGME) program, Section 340H of the Public Health Service (PHS) Act, was established by Section 5508 of Public Law 111–148. The program supports training for primary care residents (including residents in family medicine, internal medicine, pediatrics, internal medicine-pediatrics, obstetrics and gynecology, psychiatry, general dentistry, pediatric dentistry, and geriatrics) in community-based ambulatory patient care settings. The statute provides that eligible teaching health centers receive payments for both direct and indirect costs associated with training residents in community-based ambulatory patient care centers. Direct payments are designed to compensate eligible teaching health centers for those expenses directly associated with resident training, while indirect payments are intended to compensate for the additional costs of training residents in such programs. Payments are made at the beginning of the funding cycle; however, the statute provides for a reconciliation process, through which overpayments may be recouped and underpayments may be adjusted at the end of the fiscal year. This data