Rick Larsen, Jay Inslee, Norm Dicks, Adam Smith, Dave Reichert, Jaime Herrera Beutler and Jim McDermott (all of Washington), and Congresswoman Laura Richardson (California), to study the impacts and the extent to which the U.S. Harbor Maintenance Tax (HMT), other U.S. policies, and other factors may incentivize container cargo to shift from U.S. West Coast ports to those located in Canada and Mexico. These requests also asked the Commission to make legislative and regulatory recommendations to address this concern.

In recent years, there has been a steadily observed increase in the amount of U.S.-destined cargo moving through newly established west coast Canadian port Prince Rupert and the expanded Mexican port Lázaro Cárdenas. These same years saw investment in and promotion of Canadian and Mexican port and intermodal rail infrastructure, as well as changes to environmental requirements, security considerations, and customs inspection procedures.

The HMT has also been the subject of recent congressional interest. Originally enacted as part of the Comprehensive Water Resources Development Act of 1986, the HMT was devised to help fund harbor and channel maintenance by charging users of U.S. seaports at an *ad valorem* rate of 0.125%. *See* 26 U.S.C. 4461. The HMT is currently imposed only on imports and is payable at the time of unloading of the cargo in the U.S. port. *Id.* Cargo ultimately destined for U.S. inland points but entering at Canadian or Mexican seaports is not subject to the HMT.

In order to prepare the fullest response possible, the Commission now invites comment and information from all members of the interested public (whether they be located in the United States or elsewhere), including public port authorities, private marine terminal operators, ocean common carriers, ocean transportation intermediaries, supply chain experts, providers of rail and trucking services, state, local, provincial or national governments, importers, exporters and beneficial cargo owners. Comments that are specific and provide supporting data are most helpful.

1. Describe the differences, if any, in taxes, fees, laws, regulations, cargo handling, customs processes, related terminal/port procedure, infrastructure, or intermodal services between U.S. and Canadian or Mexican ports that may come into consideration when determining how to route cargo destined for U.S. inland points. Please be as specific as possible.

2. Provide your opinion and supporting data regarding the reasons vessel-operating common carriers serving the U.S., Canada and Mexico may prefer to make Mexican or Canadian ports their first North American ports of call.

3. Describe why ocean transportation intermediaries or importers may prefer to route their customers' inland U.S.-destined cargo via a Mexican or Canadian port.

4. Describe and, if possible, quantify the advantages and disadvantages a beneficial cargo owner may face when considering whether to route inland U.S.-destined cargo via a Mexican or Canadian port. Specifically, what role, if any, does the assessment of the Harbor Maintenance Tax (HMT) have on that determination? What are the other considerations? If there is a cost advantage due to lower total transportation costs (ocean, truck, rail), please quantify those differences and describe the source of any such cost differentials.

5. Please quantify the effect, if any, the change in cargo routing has had on employment in the United States.

6. Describe what volume or other incentives, bonuses or discounts, if any, are offered by ports, common carriers, terminal operators, or other entities for cargo moved through Canadian or Mexican ports and where these may be available to the shipping public.

7. Describe the advantages and/or disadvantages current transportation services via Canadian or Mexican ports may offer to U.S. exporters.

8. State your view on actions that the U.S. Government can take to improve competitiveness of U.S. ports. Of those actions, what are the most important or pressing?

Submit Comments:

Non-confidential filings may be submitted in hard copy or by email as an attachment (preferably in Microsoft Word or PDF) addressed to *secretary@fmc.gov* on or before December 22, 2011. Include in the subject line: ''U.S. Containerized Cargo Flows—Response to NOI.'' Confidential filings must be submitted in the traditional manner on paper, rather than by email. Comments submitted that seek confidential treatment must be submitted in hard copy by U.S. mail or courier. Confidential filings must be accompanied by a transmittal letter that identifies the filing as ''confidential'' and describes the nature and extent of the confidential treatment requested. When submitting comments in response to the Notice of Inquiry that contain confidential information, the confidential copy of the filing must consist of the complete filing and be marked by the filer as ''Confidential-Restricted,'' with the confidential material clearly marked on each page. When a confidential filing is submitted, an original and one additional copy of the public version of the filing must be submitted. The public version of the filing should exclude confidential materials, and be clearly marked on each affected page, ''confidential materials excluded.'' The Commission will provide confidential treatment to the extent allowed by law for those submissions, or parts of submissions, for which confidential treatment is requested. Questions regarding filing or treatment of confidential responses to this Notice of Inquiry should be directed to the Commission's Secretary, Karen V. Gregory, at the telephone number or email provided above.

By the Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2011–28878 Filed 11–7–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0444]

Gayle Rothenberg: 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 Gayle Rothenberg, MD, 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. Rothenberg was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Rothenberg was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Rothenberg failed to respond. Dr. Rothenberg's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective November 8, 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 April 20, 2010, the U.S. District Court for the Southern District of Texas entered judgment against Dr. Rothenberg for one felony count of, with intent to defraud and mislead, misbranding a drug while held for sale after shipment in interstate commerce in violation of 21 U.S.C. 331(k), 333(a)(2), 352(i)(3) and 18 U.S.C. 2, and one felony count of intentionally and knowingly, in a matter within the jurisdiction of FDA, making a false statement to an agent of FDA in violation of 18 U.S.C. 1001.

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 this conviction is as follows: Dr. Rothenberg was a physician licensed by the State of Texas as a medical doctor with a specialty in the area of anesthesiology. Dr. Rothenberg served as the medical director and operated a medical clinic in the Southern District of Texas. The medical clinic provided and performed services related to the enhancement of the physical appearance of clients and included BOTOX injections.

From February to September 2004, Dr. Rothenberg and her office manager caused staff members to order a botulinum toxin type A (TRI-toxin) product from Toxin Research International, Inc. (TRI) that was not approved by FDA. Dr. Rothenberg informed staff members that a new BOTOX product would be used to treat patients. When the orders from TRI were received, the invoice accompanying the order as well as packaging and labeling on each vial indicated that the TRI-toxin was for research purposes only and not for human use. Dr. Rothenberg was aware that the product was not intended for human use; however, she performed injections and used the TRI-toxin on patients at her medical practice from February through September 2004. Dr. Rothenberg misrepresented to patients that they were receiving injections of authentic BOTOX and BOTOX Cosmetic when in fact she knew the patients were receiving injections of non-FDA approved TRI-toxin.

On January 20, 2005, agents of FDA traveled to Dr. Rothenberg's clinic and spoke to her about whether any TRI-toxin had been ordered and used on patients of the medical clinic. Dr. Rothenberg confirmed that the nonapproved product had been ordered but stated that it had only been administered to friends and family. On February 28, 2005, agents of FDA again traveled to Dr. Rothenberg's clinic and presented 10 invoices showing that the clinic had ordered the TRI-toxin. This time Dr. Rothenberg stated that the product had been used on patients without her knowledge and approval. Dr. Rothenberg indicated that approximately 210 patients received injections of the TRI-toxin during the period of February 4 and September 8, 2004. Agents of FDA reviewed billing statements from Dr. Rothenberg's clinic and determined that the clinic received approximately $98,000 from patients who received injections of the non-FDA approved TRI-toxin.

Dr. Rothenberg pleaded guilty to, with intent to defraud or mislead, misbranding a drug while held for sale after shipment in interstate commerce, in violation of Title 21 U.S.C. 331(k), 333(a)(2), 352(i)(3) and 18 U.S.C. 2, and to making a false statement to an agent of FDA in violation of 18 U.S.C. 1001.

As a result of her convictions, on August 22, 2011, FDA sent Dr. Rothenberg 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, that Dr. Rothenberg 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. Rothenberg 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 August 30, 2011. Dr. Rothenberg 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, 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 Gayle Rothenberg has been convicted of felonies 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. Rothenberg 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) and (c)(2)(A)(ii) of the FD&C Act and section 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. Rothenberg, in any capacity during Dr. Rothenberg'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. Rothenberg 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). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Rothenberg during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Rothenberg for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2011–N–0444 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: October 25, 2011.

Armando Zamora,

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

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