(1898); *DeVeau* v. *Braisted*, 80 S.Ct. 1146 (1960).)

The preclusion of Mr. Girdhari from providing any type of service to holders of pending or approved drug product applications is not excessive in relation to the remedial goals of the GDEA. As stated above, the D.C. Circuit has held that the GDEA's prohibition on services in any capacity serves the statute's remedial purpose. (*DiCola* at 507.) Congress prescribed all services in order to avoid the serious administrative difficulties involved in distinguishing between those positions clearly related to drug regulation and those not clearly related. (*DiCola* at 507; see also *Seigel* v. *Lyng*, 851 F.2d 412, 416 (D.C. Cir. 1988).) Furthermore, the GDEA's prohibition ensures that the purposes underlying the debarment provisions are not circumvented or undermined. (*DiCola* at 507; see also *Farlee and Calfee, Inc.* v. *USDA*, 941 F.2d 964, 968 (9th Cir. 1991).) Finally, as noted above, the Supreme Court in *Hudson* v. *United States*, 118 S.Ct. 488 (1997), upheld a similar statute which, for remedial purposes, imposes a prohibition on participation in any banking activity.

Under *Hudson*, debarment pursuant to the GDEA is not so punitive either in purpose or effect as to render the penalty criminal. Thus, Mr. Girdhari's argument that debarment under the GDEA violates the Double Jeopardy Clause must fail.

E. Conclusion

Mr. Girdhari acknowledges that he was convicted as alleged by FDA in its proposal to debar him and has raised no genuine and substantial issue of fact regarding this conviction. In addition, Mr. Girdhari's legal arguments do not create a basis for a hearing and, in any event, are unpersuasive. Accordingly, the Commissioner denies Mr. Girdhari's request for a hearing.

III. Findings and Order

Therefore, the Commissioner, under section 306(a) of the act, and under authority delegated to her (21 CFR 5.10), finds that Premchand Girdhari has been convicted of a felony under Federal law for conduct: (1) Relating to the development or approval, including the process for development or approval, of a drug product (section 306(a)(2)(A) of the act); and (2) relating to the regulation of a drug product (section 306(a)(2)(B) of the act).

As a result of the foregoing findings, Premchand Girdhari is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the act, or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective January 21, 2000, (sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(ee) of the act). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Girdhari in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(7) of the act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated drug application submitted by or with Mr. Girdhari's assistance during his period of debarment (section 306(c)(1) of the act).

Mr. Girdhari may file an application to attempt to terminate his debarment, under section 306(d)(4)(A) of the act. Any such application would be reviewed under the criteria and processes set forth in section 306(d)(4)(C) and (d)(4)(D) of the act. Such an application should be identified with Docket No. 94N–0162 and sent to the Dockets Management Branch (address above). 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 Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2000.

Bernard A. Schwetz,

Acting Deputy Commissioner for Food and Drugs.

[FR Doc. 00–1406 Filed 1–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0120]

Safety of Imported Foods; Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing two public meetings on the safety of imported foods. These meetings are intended to give an overview of, and discuss the six specific objectives of, the proposed plan announced by the President in his radio address of December 11, 1999. FDA and the U.S. Customs Service have developed proposed new operational procedures to accomplish these objectives. The public meetings also are intended to give the public an opportunity to comment on the proposed procedures.

DATES: See Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: For general information regarding this document: Mary J. Ayling, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 200 C St. SW., Rm. 3823, Washington, DC 20204, 202–260–5348, FAX 202–260–9653, e-mail: mayling@bangate.fda.gov. The comprehensive plan is available at http://www.foodsafety.gov.

SUPPLEMENTARY INFORMATION: On July 3, 1999, the President announced an initiative to ensure the safety of imported food by directing the Secretaries of the U.S. Department of Health and Human Services and the U.S. Department of Treasury to develop new operational procedures to protect public health. This initiative is geared to optimize the statutory authorities and resources available to FDA and the U.S. Customs Service to take whatever steps are feasible to protect consumers from unsafe imported foods. The President directed the agencies to target unscrupulous importers who violate the rules and work to subvert the system by moving unsafe foods into U.S. markets.

The agenda for the public meetings will include the following six specific objectives emphasized in the President's directive: (1) To prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA; (2) destroy imported food that poses a serious public health threat; (3) prohibit the reimportation of food that has been previously refused admission and has not been brought into compliance and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons; (4) set standards for the use of private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the United States; (5) increase the amount of the bond posted for

imported foods when necessary to deter premature and illegal entry into the United States; and (6) enhance enforcement against violations of U.S. laws related to the importation of foods, including through the imposition of civil monetary penalties.

The public meetings also will include an overview of the President's directive and a review of the new operational procedures proposed to accomplish each of the six objectives. The meetings will provide a forum for discussion of the proposed procedures. In addition to a plenary session, the meetings will provide the opportunity for additional discussion of the specific objectives. Three breakout sessions to discuss the following are planned: (A) Secured storage, increased bonds, enforcement activities; (B) destruction and marking of refused foods; and (C) standards for the use of private laboratories. The U.S. Customs Service will jointly present the objectives with FDA. Transcripts of the public meetings are not planned.

If you would like to attend a public meeting, send registration information (including name, title, firm name, mailing address, telephone number, fax number, e-mail address, and selection of breakout session A, B, or C) to the contact person listed for the meeting you wish to attend at least 7 days prior to the meeting date. Attendance will be limited due to seating capacity. There is no registration fee for this meeting.

Meeting Address	Date and Local Time	FDA Contact Person
IRVINE: Los Angeles District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612.	Thursday, February 10, 2000, 9 a.m. to 12 noon.	Irene Gomez, 222 West 6th St., suite 700, San Pedro, CA 90731, 310–831–6123, ext. 103, e-mail: igomez@ora.fda.gov.
WASHINGTON: Hubert H. Humphrey Bldg., 200 D St. SW., rm. 800, Washington, DC 20204.	Thursday, February 17, 2000, 9 a.m. to 12 noon.	Peter A. Salsbury, Executive Operations Staff (HFS–022), 200 C St. SW., Washington, DC 20204, 202–205–4299, e-mail: psalsbur@bangate. fda.gov.

Dated: January 12, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–1410 Filed 1–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99P–1720]

Approval of an Alternate Requirement of the User Labeling Requirements for Devices Containing Dry Natural Rubber that Contact Humans; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Approval of an Alternative Requirement of the User Labeling Requirements for Devices that Contain Dry Natural Rubber that Contact Humans.'' FDA granted a petition submitted by the Health Industry Manufacturers Association (HIMA), on behalf of in vitro diagnostic device (IVD) manufacturers, that requested a variance from placing the warning statement about dry natural rubber on the immediate IVD package (vial) label. FDA is announcing the availability of its response to HIMA's petition in order to inform affected manufacturers and the public.

ADDRESSES: Submit written requests for single copies on a 3.5 diskette of the document entitled ''Approval of an Alternate Requirement of the User Labeling Requirements for Devices that Contain Dry Natural Rubber that Contact Humans'' to the contact person named below. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the alternative requirement document.

FOR FURTHER INFORMATION CONTACT: John J. Farnham, Center for Devices and Radiological Health (HFZ–321), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20852, 301–594–4616.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 30, 1997 (62 FR 51021), FDA issued a final rule, codified in 21 CFR § 801.437(e), requiring labeling statements on medical devices containing dry natural rubber that are intended to contact or likely to contact humans. The rule became effective on September 30, 1998. On June 3, 1999, HIMA requested a variance for in vitro diagnostic products that have vial labels too small to accommodate the required statement. The petition said that manufacturers of the products could place the warning on the outer package, as well as on a package insert. On September 10, 1999, FDA issued a letter granting HIMA's petition.

II. Electronic Access

In order to receive the document entitled ''Approval of an Alternative Requirement of the User Labeling Requirements for Devices that Contain Dry Natural Rubber that Contact Humans,'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from the touch-tone telephone. At the first