Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

1. A Pilot Study to Evaluate CDC's 1998 Guidelines for the Treatment of Sexually Transmitted Diseases Among Clinicians in Two Managed Care Organizations—The National Center for HIV, STD, and TB Prevention (NCHSTP) is proposing a pilot survey of 1,000 practitioners in two managed care plans to evaluate how CDC's most recent edition (1998) of the Sexually Transmitted Disease (STD) Treatment Guidelines influence practice. The pilot survey will be conducted in two large, mixed model managed care plans which are located in two different geographic regions of the U.S. The survey is expected to last from 3–6 months. The CDC periodically publishes national guidelines on the diagnosis and treatment of sexually transmitted diseases; however, little is known about the impact of the guidelines on clinical practice and treatment choices, the practical use of the guidelines, or utility to providers. Data gathered from this study will provide preliminary information about the extent to which providers are aware of the guidelines, their access to the guidelines, their use of the guidelines, and factors that enable or preclude use of the guidelines. The information will assist CDC in determining ways to improve practitioners' understanding and promote utilization of the guidelines; determine ways to make them more available for medical practitioners; and increase the use of the guidelines in appropriate medical practices. The total annual burden hours are 334.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (in hours)
Managed care physicians or advance practice Nurses	1,000	1	.334

Dated: January 14, 2000.

Nancy Cheal, Ph.D.,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–1452 Filed 1–20–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0162]

Premchand Girdhari; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying the request of Premchand Girdhari, 643 Rassbach St., Eau Claire, WI 54701, for a hearing, and is issuing a final order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. Girdhari 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 Mr. Girdhari was convicted of two felonies under Federal law relating to the regulation of a drug product under the act. Mr. Girdhari has failed to file with the agency information and analyses sufficient to create a basis for a hearing concerning this action.

EFFECTIVE DATE: January 21, 2000.

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Richard L. Arkin, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl. Rockville, MD 20855, 301–827–0141, FAX 301–827–5510, e-mail ''rarkin@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

On May 8, 1991, United States District Court for the Western District of Wisconsin accepted a plea of guilty from Premchand Girdhari, former President of Radix Laboratories, Inc., to a two count information, for making false statements and distributing adulterated drugs with the intent to defraud and mislead in violation of the act, Federal felony offenses under 18 U.S.C. 1001 and sections 301(a) and 303(b) of the act (21 U.S.C. 331(a) and 333(b)). On July 8, 1991, judgment against Mr. Girdhari was entered and the court advised him of his sentence. The court amended its judgment to correct a clerical error but otherwise affirmed its earlier judgment and sentence on October 7, 1991.

Mr. Girdhari was the president of Radix Laboratories, Inc., a Wisconsin corporation that manufactured a variety of animal drugs. In that capacity, he caused to be introduced into commerce adulterated drugs. Specifically, Mr. Girdhari marketed the drug ''Antihistamine (2%),'' which drug is adulterated within the meaning of (section 501(a)(5) and (a)(2)(B) of the act (21 U.S.C. 351(a)(5) and (a)(2)(B)), because the drug was not the subject of the necessary FDA approvals nor was it manufactured in conformity with good manufacturing practice. He also knowingly and willfully made a false statement in a matter, within the jurisdiction of FDA, related to FDA's regulation of the injectable animal drug, ''Cal–Plex.''

Section 306(a)(2) of the act (21 U.S.C. 335a(a)(2)) mandates 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 act. Under section 306(l)(2) of the act, mandatory debarment applies when an individual is convicted within 5 years preceding the initiation of the agency's action to debar. Section 306(c)(2)(A)(ii) of the act requires that such debarment be permanent.

FDA has made a finding that Mr. Girdhari was convicted of two felonies under Federal law for conduct relating to the regulation of Radix drug products. Mr. Girdhari's first felony conviction under 18 U.S.C. 1001 was for making a false statement to FDA about the manufacture and distribution of the unapproved injectable animal drug, ''Cal–Plex.'' The information he falsified concerns matters that affect FDA's regulatory decisions about drug products. His second felony conviction under section 301(a) of the act was for violations of provisions of the act that prohibit introduction and delivery for introduction into interstate commerce of any drug that is adulterated, a felony conviction under Federal law for conduct relating to the regulation of a drug product under the act.

In a certified letter received by Mr. Girdhari on October 17, 1994, the Interim Deputy Commissioner for Operations of FDA proposed to issue an order under section 306(a)(2) of the act permanently debarring Mr. Girdhari

from providing services in any capacity to a person that has an approved or pending drug product application. The letter offered Mr. Girdhari an opportunity for a hearing on the agency's proposal to issue such an order. FDA based the proposal to debar Mr. Girdhari on its finding that he had been convicted of two felonies under Federal law for conduct relating to the regulation of Radix's drug products.

The certified letter also informed Mr. Girdhari that his request for a hearing could not rest upon mere allegations or denials but must present specific facts showing that there was a genuine and substantial issue of fact requiring a hearing. The letter also notified Mr. Girdhari that if it conclusively appeared from the face of the information and factual analyses in his request for a hearing that there was no genuine and substantial issue of fact that precluded the order of debarment, FDA would enter summary judgment against him and deny his request for a hearing.

In a letter dated November 10, 1994, Mr. Girdhari requested a hearing on the proposal and indicated that further information would be submitted. On December 14, 1994, Mr. Girdhari submitted arguments and information in support of his hearing request.

In his request for a hearing, Mr. Girdhari acknowledges that he pleaded guilty to offenses charged under 18 U.S.C. 1001 and sections 301(a) and 303(b) of the act and that convictions and sentencing for these offenses were entered pursuant to the guilty pleas on July 8, 1991. However, Mr. Girdhari argues that FDA's findings based on the conviction are incorrect and that the agency's proposal to debar him is unconstitutional.

The Commissioner of Food and Drugs (the Commissioner) has considered Mr. Girdhari's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing. Moreover, the legal arguments that Mr. Girdhari offers do not create a basis for a hearing. (See 21 CFR 12.24(b)(1).) Mr. Girdhari's arguments are discussed below.

II. Mr. Girdhari's Arguments in Support of a Hearing

A. Retroactive Application of Statute Is Improper

Mr. Girdhari contends that ''retroactive application'' of the Generic Drug Enforcement Act (GDEA) of 1992 (Pub. L. 102–282), is improper and argues that Congress did not intend that the debarment provisions of the GDEA be applied retroactively.

Mr. Girdhari states that the GDEA was not enacted until May 13, 1992, which was subsequent to the date of his conviction on July 8, 1991. He contends that he could not have anticipated the collateral legal consequences of the GDEA in plea negotiations, and had he known of the potential for possible future debarment, he either might not have agreed to plead guilty to violations that could be used as the foundation for debarment, or he might have pleaded innocent and sought a trial by jury. Thus, he contends that debarment would mean that he would suffer an unforeseen and substantial additional penalty of permanent prohibition from providing services in any capacity to a person with an approved or pending drug application.

Mr. Girdhari argues that under the Supreme Court's holding in *Landgraf* v. *USI Film Products, et al.*, 114 S.Ct. 1483 (1994), legislative enactments will not be presumed to apply retroactively unless Congress has expressed clear intent to the contrary. Mr. Girdhari further argues that neither the GDEA's provisions nor its legislative history constitute a clear expression of retroactive intent.

The Supreme Court in *Landgraf* v. *USI Film Products*, 114 S.Ct. 1483 (1994), clarified the standard to be applied in determining whether or not a statute operates retroactively. Under the analysis established in *Landgraf*, a statute applies retroactively if ''Congress has expressly prescribed'' such application. (*Landgraf*, 114 S.Ct. 1505.) If the statute contains ''no such express command,'' then the statute can only be applied retroactively if the statute would not have a ''retroactive effect,'' which ''would impair a party's rights which he possessed when acting, increase a party's liability for past conduct, or impose new duties with respect to transactions already completed.'' (Id.)

Mr. Girdhari's argument that the GDEA cannot be applied retroactively under the standard set forth in *Landgraf* is unpersuasive. Mr. Girdhari's debarment is permissible because his debarment does not have a ''retroactive effect'' as that term is defined in *Landgraf*. Moreover, even if Mr. Girdhari's debarment were viewed as retroactive, the plain language of the GDEA evinces a clear congressional intent to debar specified individual felons from future participation in the pharmaceutical industry, irrespective of whether their violations predate the enactment of the GDEA. Finally, the remedial goals of the GDEA demonstrate Congress's intent to apply debarment under the GDEA to individuals convicted before the statute's amendment.

1. Debarment Is Not Retroactive Under Landgraf

Contrary to Mr. Girdhari's argument, Landgraf does not bar the future application of a statute premised upon events predating its enactment unless the new statute has true ''retroactive effect.'' (*Landgraf*, 114 S.Ct. 1505.)

Statutes authorizing injunctive or other prospective relief do not have retroactive effect, even if they are predicated upon events antecedent to the enactment of the statute. (*Landgraf*, 114 S.Ct. 1501.) Although the issuance of an injunction is invariably precipitated by past legal violations or other misconduct, ''the purpose of prospective relief is to affect the future rather than remedy the past,'' *id.* at 1525 (Scalia, J., concurring), and the injunction itself operates solely ''*in futuro*,'' affecting only conduct that occurs after it has been issued. (*Id.* (*quoting American Steel Foundries* v. *Tri–City Central Trades Council*, 257 U.S. 184, 201 (1921)).) Thus, ''(w)hen (an) intervening statute authorizes or affects the propriety of prospective relief, application of the new provision is not retroactive.'' (*Landgraf*, 114 S.Ct. at 1501; see also *American Steel Foundries*, 257 U.S. at 201 (because relief by injunction operates only in futuro, right to such relief must be determined by law in effect at time injunction is entered).)

Statutes that operate in futuro are not retroactive within the meaning of *Landgraf*, even if their application is triggered by events antecedent to the enactment of the statute. (See *Bell Atlantic Telephone Companies* v. *FCC*, 79 F.3d 1195, 1207 (D.C. Cir. 1996) (FCC ''add-back order'' was not ''retroactive'' within the meaning of *Landgraf* and was purely prospective, because even though the order required the assessment of past earnings, such an order determined how much a carrier could charge for future services); *Scheidemann* v. *INS*, 83 F.3d 1517, 1523 (3rd Cir. 1995) (an amendment to immigration law, ''[l]ike statutes altering the standards for injunctive relief,'' had only a ''prospective'' impact and, thus, was not retroactive under *Landgraf*).)

Debarment under the GDEA, like an injunction, plainly does not have retroactive effect within the meaning of *Landgraf*. Unlike the compensatory damages at issue in *Landgraf*, which were ''quintessentially backward-looking,'' *Landgraf*, 114 S.Ct. at 1506, the purpose of debarment is to restrict future conduct, notwithstanding the fact that its application is triggered by past

events. For purposes of retroactivity analysis, debarment orders are indistinguishable from injunctions and other forms of prospective relief. Mr. Girdhari's debarment is, in practical effect, simply a statutorily-mandated administrative injunction prohibiting him from engaging in certain conduct in the future.

As the Courts of Appeals for the District of Columbia and the Seventh Circuits have recognized, debarment under the GDEA is a forward-looking remedial action; it does not impose additional punishment for past conduct but, rather, reflects a congressional judgment ''that the integrity of the drug industry, and with it public confidence in that industry, will suffer if those who manufacture drugs use the services of someone who has committed a felony subversive of FDA regulation.'' (*DiCola* v. *FDA*, 77 F.3d 504, 507 (D.C. Cir. 1996); see also *Bae* v. *Shalala*, 44 F.3d 489, 493, 496 (7th Cir. 1995) (debarment under GDEA is solely remedial).)

2. The Plain Language of the GDEA Demonstrates That Congress Intended That FDA Debar Individuals Whose Criminal Activity Predates the Enactment of the GDEA

Even if debarment were viewed as having ''retroactive effect,'' Mr. Girdhari's debarment is still permissible under *Landgraf* because the plain language of the GDEA evinces a clear congressional intent that the statute be applied to events that occurred prior to its enactment.

First, section 306(l)(2) of the act, which sets forth the effective dates for various provisions of the act, demonstrates that Congress intended that section 306(a)(2) be applied retroactively. Section 306(l)(2) of the act states that section 306(a) shall not apply to a conviction which occurred more than 5 years before the initiation of an agency action. This language indicates that an applicable conviction may be used as the basis for debarment, so long as it occurred no more than 5 years prior to the initiation of debarment proceedings. At the time of the passage of the statute on May 13, 1992, at which point the agency could initiate a debarment action under section 306(a)(2) of the act, any applicable conviction up to 5 years before such date could serve as the basis for the debarment. Thus, the statute addresses retroactivity, and sets forth the boundaries of its application.

Second, the use of limiting language in section 306(a)(1) of the act with regard to mandatory debarment of corporations and the omission of such language in section 306(a)(2) with regard to mandatory debarment of individuals also demonstrates that Congress intended that the latter section be applied retroactively. Section 306(a)(1) of the act provides that mandatory debarment of corporations applies only to convictions ''after the date of enactment of this section.'' However, section 306(a)(2) of the act, which pertains to mandatory debarment of individuals, does not contain this limiting language. A commonly used rule of statutory construction states that where Congress includes particular language in one section of a statute but omits such language in another section of the same act, it is generally presumed that Congress acts intentionally and purposefully in the disparate inclusion or exclusion. (*I.N.S.* v. *Cardoza–Fonseca*, 107 S.Ct. 1207, 1213 (1987) (citing *Russelo* v. *United States*, 104 S.Ct. 296, 300 (1983)).) Accordingly, here Congress intended that section 306(a)(2) of the act have retroactive effect because it did not specify in section 306(a)(2) that it applied only to convictions ''after the date of enactment of this section'' as specified in section 306(a)(1) of the act.

The negative inference drawn from the omission in section 306(a)(2) of the act of the language in section 306(a)(1), which limits the latter section's effect to convictions after the date of enactment, arises directly from the disparate treatment of two provisions within a subsection which are much more closely related than the diverse sections of the Civil Rights Act of 1991 cited by appellant in *Landgraf*. The debarment provisions at issue involve two types of mandatory debarment, individual and corporate, while the provisions of the Civil Rights Act at issue in *Landgraf* involved the foreign application of Title VII, punitive and compensatory damages, and the right to a jury trial. Thus, the related debarment provisions make a clear showing of retroactive intent.

Moreover, even under *Landgraf*, ''negative inference'' may provide evidence of congressional intent regarding retroactive application of a statute. Courts applying the *(Landgraf)* analysis have found a sufficient showing of congressional intent based on negative inference drawn from the statutory language to justify retroactive application of the statute. (See *Scheidemann* v. *INS*, 83 F.3d 1517, 1524 (3rd Cir. 1996); *Nevada* v. *United States*, 925 F. Supp. 691, 693 (D. Nev. 1996) (the ''(*Landgraf*) Court did not preclude all future use of a negative inference analysis in support of retroactive intent'').) Similarly, the negative inference in the debarment provisions of the GDEA demonstrates the clear congressional intent for retroactive application of the statute.

3. The Remedial Goals of the GDEA Demonstrate That Congress Intended the GDEA To Be Applied Retroactively

The circumstances giving rise to the passage of the GDEA demonstrate that Congress intended the statute to be applied retroactively. Congress enacted the GDEA in order to restore the integrity of the drug approval process and to protect the public health. (See Generic Drug Enforcement Act of 1992, Pub. L. 102–282, Section 102, 106 Stat. 149, 149 (1992).) In order to restore consumer confidence in the drug industry, Congress intended that individuals convicted of felonies relating to the development or approval, or otherwise relating to the regulation, of drug products be prohibited from continuing to work in that industry. (See section 306(a)(2) of the act.) Construing the GDEA to permit the debarment of individuals whose felonious conduct occurred prior to the GDEA's enactment serves these remedial goals of the statute.

In *Bae* v. *Shalala*, 44 F.3d 489 (7th Cir. 1995), the Seventh Circuit upheld FDA's debarment under the GDEA of the former president of a generic drug manufacturing firm, based on his antecedent conviction for providing an ''unlawful gratuity'' to an FDA official. Although Bae argued that his debarment was ''retroactive punishment'' in violation of the Ex Post Facto Clause of the U.S. Constitution, the Seventh Circuit found that Bae's debarment was remedial, not punitive, and therefore did not violate the Ex Post Facto Clause. (*Bae*, 44 F.3d at 493, 495–96.) The Seventh Circuit recognized that, to achieve its remedial goal of restoring consumer confidence in the generic drug industry, Congress appropriately determined that it could prohibit felons such as Bae from future activity in the industry. (*Id.* at 496.)

Likewise, in *DiCola* v. *FDA*, 77 F.3d 504 (D.C. Cir. 1996), the Court of Appeals for the District of Columbia Circuit upheld the debarment of another former generic drug company executive, rejecting ex post facto, double jeopardy, and vagueness challenges to his debarment. The D.C. Circuit, like the Seventh Circuit, found that the GDEA legitimately achieved its remedial purposes by barring convicted felons from future contact with the industry. (*DiCola*, 77 F.3d at 507.)

The GDEA is not punitive, but accomplishes remedial goals by removing convicted felons from the industry they have exploited. The

remedial goals would not be achieved, however, if individuals convicted of felonies prior to the GDEA's enactment continued to work in the drug industry. Retroactive application of the GDEA is not only permissible, but necessary, because Congress' aim of restoring consumer confidence in the drug industry is only served by applying the statute to permit the debarment of individuals, like Mr. Girdhari, whose violations predate, and, in some cases, precipitated, the statute's enactment. (See *United States* v. *The Schooner Peggy*, 5 U.S. (1 Cranch) 103 (1801) (courts to adopt interpretation that serves overall purposes of the statute); see also *Scheidemann* v. *INS*, 83 F.3d 1517, 1521 (3rd Cir. 1996) (Congress's intent to be deduced from statutory scheme as a whole).) Thus, the remedial goals of the GDEA demonstrate that Congress intended the statute to be applied retroactively.

B. Retroactive Application of the Statute Violates the Ex Post Facto Clause

Mr. Girdhari argues that retroactive application of the debarment provisions of the GDEA to him violates the Ex Post Facto Clause of the U.S. Constitution because the debarment provisions, which were not in effect at the time of his criminal conduct, are punitive in nature.

An ex post facto law is one that reaches back to punish acts that occurred before the enactment of a law or that adds a new punishment to one that was already in effect when the crime was committed. (*Ex Parte Garland*, 4 Wall. 333, 337, 18 L.Ed. 366 (1866); *Collins* v. *Youngblood*, 110 S.Ct. 2715 (1990).) Mr. Girdhari claims that the debarment provisions are punitive in nature for several reasons.

First, Mr. Girdhari argues that the debarment provisions are punitive in nature because the GDEA punishes individuals for past behavior and deters future misconduct both by the individual who is debarred and by other individuals in the drug industry. Second, he argues that the debarment provisions' permanent prohibition on providing services ''in any capacity'' to a drug company constitutes an overly broad restriction which is punitive in nature. Third, he argues that such an overly broad restriction distinguishes his case from *DeVeau* v. *Braisted*, 80 S.Ct. 1146, 1155 (1960), in which the Supreme Court found the retroactive application of a law which prohibited convicted felons from union office was remedial in nature because the restriction was ''a relevant incident to a regulation of a present situation.'' Finally, he argues that application of the debarment provisions to individuals convicted of Federal felonies related to the regulation of animal drugs would not serve any remedial purpose, because the statute's remedial purpose is limited to ensuring the integrity of the human generic drug industry, safeguarding human health, and restoring human consumer confidence.

Mr. Girdhari's arguments that application of the debarment provisions of the act to him is prohibited by the Ex Post Facto Clause are unpersuasive. In determining whether a statute violates the Ex Post Facto Clause, the critical consideration is whether the provision is remedial or punitive in nature. Because the intent underlying debarment under section 306(a)(2) is remedial rather than punitive, application of the section to him does not violate the Ex Post Facto Clause. Mr. Girdhari's arguments are addressed in turn below.

1. Remedial Nature of the GDEA

Mr. Girdhari contends that the GDEA is punitive because it punishes past behavior and deters future misconduct. It is clear, however, that the statute is remedial in nature. Congress created the GDEA in response to findings of fraud and corruption in the generic drug industry. Congress made explicit findings regarding the necessity of the GDEA that were incorporated into section 1 of the statute and also were made part of the legislative history. (See H.R. Rep. No. 272, 102d Cong., 1st Sess. 10–11 (1991), reprinted in 1992 U.S.C.C.A.N. 103, 104–105.) Congress found that ''(1) there is substantial evidence that significant corruption occurred in FDA's process of approving drugs under abbreviated drug applications, (2) there is a need to establish procedures designed to restore and to ensure the integrity of the abbreviated drug application process and to protect the public health, and (3) there is a need to establish procedures to bar individuals who have been convicted of crimes pertaining to the regulation of drug products from working for companies that manufacture or distribute such products.'' (Generic Drug Enforcement Act of 1992, Pub. L. 102–282, Section 102, 106 Stat. 149, 149 (1992).)

Moreover, the Courts of Appeals for the District of Columbia Circuit and Seventh Circuits have held that the debarment provisions do not violate the Ex Post Facto Clause, because the provisions are remedial in nature, rather than punitive. (*DiCola* v. *F.D.A.*, 77 F.3d 504, 507 (D.C. Cir. 1996); *Bae* v. *Shalala*, 44 F.3d 489, 493 (7th Cir. 1995).) The court in Bae concluded, ''The clear and unambiguous intent of Congress in passing the GDEA was to purge the generic drug industry of corruption and to restore consumer confidence in generic drug products. The GDEA's civil debarment penalty is solely remedial * * *'' (*Bae* at 493.) The court in DiCola agreed with this conclusion. (*DiCola* at 507.)

Furthermore, the Supreme Court has long held that statutes that deny future privileges to convicted offenders because of their previous criminal activities in order to ensure against corruption in specified areas do not punish those offenders for past conduct and, therefore, do not violate the ex post facto prohibitions. (See, e.g., *Hawker* v. *New York*, 18 S.Ct. 573 (1898) (physician barred from practicing medicine for a prior felony conviction); *DeVeau* v. *Braisted*, 80 S.Ct. 1146 (1960) (convicted felon's exclusion from employment as officer of waterfront union is not a violation of the Ex Post Facto Clause).)

Contrary to Mr. Girdhari's contentions, the remedial nature of the GDEA is not diminished simply because the GDEA deters debarred individuals and others from future misconduct. The Supreme Court in *U.S.* v. *Halper*, 109 S.Ct. 1892, 1901, n.7 (1989), noted that ''for the defendant even remedial sanctions carry the sting of punishment.'' The Court found that such deterrent effects would not diminish the remedial nature of a civil sanction. (*Halper* at 1902.) Furthermore, the Supreme Court in *Hudson* v. *United States*, 118 S.Ct. 488, 494 (1997), stated, ''We have since [the *Halper* ruling] recognized that **all** civil penalties have some deterrent effect'' (emphasis added). (See *Department of Revenue of Mont.* v. *Kurth Ranch*, 114 S.Ct. 1937, 1945, n.14 (1994); *United States* v. *Ursery*, 116 S.Ct. 2135, 2145, n. 2 (1996).) The Court continued, ''(b)ut the mere presence of this purpose (deterrence) is insufficient to render a sanction criminal * * *'' (*Hudson* at 496.) As the court in *Bae* stated, ''The punitive effects of the GDEA are merely incidental to its overriding purpose to safeguard the integrity of the generic drug industry while protecting public health.'' (*Bae* at 493; see also *Mannochio* v. *Kusserow*, 961 F.2d 1539, 1542 (11th Cir. 1992).) Thus, Mr. Girdhari's argument that any incidental deterrent effects cause the statute to be punitive is without merit.

2. Permanent Prohibition on Services in Any Capacity

Mr. Girdhari argues that the GDEA's permanent prohibition on providing services ''in any capacity'' to a company

with an approved or pending drug application is an overly broad restriction which is punitive in nature.

a. *Prohibition on services in any capacity*. Mr. Girdhari contends that the prohibition on providing services ''in any capacity'' would include services that have ''no rational connection'' to the drug approval process. Mr. Girdhari argues that such a prohibition would not serve any remedial purpose of the statute and would constitute punishment for the debarred individual. Mr. Girdhari's arguments are unpersuasive for the reasons given below.

Congress enacted the GDEA in order to restore the integrity of the drug approval process and to protect the public health. All facets of the drug industry were implicated in the scandals that led to the enactment of the GDEA, including generic drug company executives, scientists at both generic and innovator firms, consultants, research laboratories, and FDA employees. (See H.R. Rep. No. 102–272, 102d Cong., 1st Sess., at 14 (1991).) In light of this background, Congress rationally concluded that in order to ensure the integrity of the drug approval process and to protect the public health, it was necessary, among other things, to unequivocally exclude from the drug industry those individuals, like Mr. Girdhari, who had previously engaged in fraudulent or corrupt acts with respect to the regulation of drugs. The D.C. Circuit in *DiCola* held that the debarment provisions' prohibition on services ''in any capacity'' serves the statute's remedial purpose. (*DiCola* at 507.) As the Seventh Circuit noted in *Bae*, ''the duration or severity of any employment restriction will not mark it as punishment where it is intended to further a legitimate governmental purpose.'' (*Bae* at 495.)

The breadth of the debarment imposed under the GDEA furthers the statute's remedial goals by promoting efficient administration of the debarment provisions, ensuring uniform treatment of offenders, and restoring public confidence in the pharmaceutical industry. Congress prohibited all services in the GDEA in order to avoid the serious administrative difficulties involved in distinguishing between those positions clearly related to drug regulation and those not so related. (*DiCola* at 507.) These difficulties would include the problem of ascertaining the exact nature of an employee's or contractor's relationship with an employer or the person entering the contract, as well as defining what constitutes a sufficient nexus with the regulatory scheme under all circumstances. (*DiCola* at 507; see also *Siegel* v. *Lyng*, 851 F.2d 412, 416 (D.C. Cir. 1988).)

Additionally, the GDEA's prohibition on services ''in any capacity'' ensures that the purposes underlying the debarment sanction are not circumvented or undermined. Any attempt to list or define particular areas of employment that are prohibited to debarred individuals would be subject to creative exploitation by those determined to reenter a familiar field. The D.C. Circuit in *DiCola* concluded that the agency would be especially concerned about ''any employment that might create an opportunity for regular and frequent contact'' between a debarred individual and the management of a drug company, because ''[t]he agency would find it very difficult, if not impossible, to assure itself and the public that [the individual] is not, through that contact, actually selling advice or other services related to the circumvention of Federal regulation.'' (*DiCola* at 507; see also *Farlee and Calfee, Inc.* v. *USDA*, 941 F.2d 964, 968 (9th Cir. 1991).)

Furthermore, courts have upheld many other types of debarment provisions that involved employment restrictions that were as broad, or broader than, the GDEA's prohibition on services ''in any capacity.'' For instance, the United States Supreme Court in *Hudson* v. *United States*, 118 S.Ct. 488 (1997), upheld a broad sanction that debarred participation in *any* banking activities. Furthermore, the Seventh Circuit Court of Appeals in *United States* v. *Furlett*, 974 F.2d 839, 844 (7th Cir. 1992), upheld a debarment order that prohibited a commodities trader from trading on any contract market, even as a retail customer of another broker. (See also *Manocchio* v. *Kusserow*, 961 F.2d 1539, 1541–42 (upholding exclusion from participation in *any* Medicare program); *United States* v. *Bizzell*, 921 F.2d at 267 (upholding exclusion from participation in *any* Housing and Urban Development program).)

Finally, Mr. Girdhari cites *Kennedy* v. *Mendoza-Martinez*, 83 S.Ct. 554, 568 (1963), in support of his argument that the prohibition on services ''in any capacity'' is not related to any remedial purpose of the GDEA. Specifically, Mr. Girdhari notes that the Supreme Court held in Kennedy that the excessive effect of a sanction relative to its remedial purpose is relevant in determining whether the sanction is civil or criminal. (*Kennedy* at 568.) The decision in *Kennedy*, however, does not support Mr. Girdhari's argument that debarment is a punitive sanction.

The Supreme Court in *Kennedy* listed the relevant factors, including whether a sanction's effect is excessive in relation to its nonpunitive purpose, to determine whether a civil penalty removing an individual's citizenship was in effect a criminal penalty requiring the procedural safeguards of the Fifth and Sixth Amendments. (*Kennedy* at 567–68.) As shown above, the GDEA's prohibition on providing services ''in any capacity'' to individuals with pending or approved drug product applications is necessary to promote the remedial purpose of the statute and, thus, is not excessive. Furthermore, the Supreme Court in *Hudson* v. *United States*, 118 S.Ct. 488 (1997), held that a debarment order was not a criminal punishment based, in part, on the factors set forth in *Kennedy*. As noted above, the debarment order at issue in *Hudson* was as broad as the GDEA's prohibition on providing services ''in any capacity''. Therefore, by the reasoning in *Kennedy*, the GDEA's prohibition on providing services ''in any capacity'' is not punitive.

b. *Permanence of the prohibition*. As for the prohibition's duration, both the District of Columbia and the Seventh Circuits have held that the permanence of the debarment is rationally related to the remedial goals of the statute. (*DiCola* at 507; *Bae* at 495.) The District of Columbia Circuit in *DiCola* stated, ''The permanence of the debarment can be understood, without reference to punitive intent, as reflecting a congressional judgment that the integrity of the drug industry, and with it public confidence in that industry, will suffer if those who manufacture drugs use the services of someone who has committed a felony subversive of FDA regulation.'' (*DiCola* at 507.) The Seventh Circuit in *Bae* emphasized that permanent debarment from providing services in any capacity is ''not disproportionate to the remedial goals of the GDEA or to the magnitude of (the defendant's) wrongdoing.'' (*Bae* at 496.) Additionally, the Supreme Court has upheld other statutes which, for remedial purposes, permanently bar a class or group of individuals from certain occupations due to a prior criminal conviction. (See *Hawker* v. *New York*, 18 S.Ct. 573 (1898); *DeVeau* v. *Braisted*, 80 S.Ct. 1146 (1960).) Therefore, Mr. Girdhari's argument that the permanent nature of the debarment is punitive must fail.

3. DeVeau

Mr. Girdhari contends that the GDEA can be distinguished from *DeVeau* because the permanent prohibition on

providing services ''in any capacity'' to an individual with an approved or pending drug application cannot be justified as ''incident to a regulation of a present situation'' and thus reveals punitive intent. However, the debarment provisions' prohibitions are clearly incident to regulation of a present situation and, as such, the Court's reasoning in *DeVeau* applies.

In *DeVeau*, the Court upheld a law that prohibited a convicted felon from employment as an officer in a waterfront union. The purpose of the law was to remedy the past corruption and to ensure against future corruption in the waterfront unions. The Court in *DeVeau*, 80 S.Ct. at 1155, stated:

The question in each case where unpleasant consequences are brought to bear upon an individual for prior conduct, is whether the legislative aim was to punish that individual for past activity, or whether the restriction of the individual comes about as a relevant incident to a regulation of a present situation * * *.

As with *DeVeau*, the legislative purpose of the relevant statute here is to ensure that fraud and corruption are eliminated from the drug industry and, therefore, the public's confidence in that industry will be restored. The restrictions placed on individuals convicted of a felony under Federal law are not intended as punishment but are intended to preserve the integrity of the drug approval process and protect the public health, purposes which are clearly ''incident to a regulation of a present situation'' and, as such, consistent with *DeVeau*. Therefore, this argument must also fail.

4. Applicability of GDEA to Animal Drug Convictions

Mr. Girdhari argues that the debarment provisions of section 306(a)(2) of the act cannot be retroactively applied to him because the remedial purposes of the GDEA are unrelated to the activities upon which his conviction was based. He contends that Congress intended the GDEA to apply to convictions involving human drugs, not animal drugs. Therefore, he concludes that retroactive application of section 306(a)(2) of the act to him would not serve any remedial purpose.

Mr. Girdhari's argument that section 306(a)(2) of the act cannot be retroactively applied to convictions involving animal drugs is unpersuasive. Congress clearly intended the GDEA to apply to convictions involving animal drugs. The Supreme Court has held repeatedly that the starting point for determining the meaning of a statute is the plain language of the statute. (*Norfolk & Western Railway Company* v. *American Train Dispatchers Association*, 111 S.Ct. 1156, 1163 (1991); *Mallard* v. *U.S. District Court for the Southern District of Iowa*, 109 S.Ct. 1814, 1818 (1989).) If the language of the statute is clear on its face, that language must ordinarily be regarded as conclusive. (*Negonsott* v. *Samuels*, 113 S.Ct. 1119, 1122 (1993).)

It is clear from the plain language of the GDEA that it explicitly includes animal drugs within its scope. Section 306(a)(2) of the act applies to ''an individual who has been convicted of a felony under Federal law for conduct relating to the regulation of *any drug product.*'' (emphasis added.) Additionally, section 306(a)(2) of the act debars such individual ''from providing services in any capacity to a person that has an approved or pending *drug product* application.'' (emphasis added.) Section 201(dd) of the act (21 U.S.C. 321(dd)) defines drug product specifically for the purpose of section 306 of the act as a drug subject to regulation under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or section 351 of the Public Health Service Act. Section 512 of the act regulates both pioneer and generic animal drugs.

The intent of Congress to apply the debarment provisions to animal drug convictions is clearly shown by the reference to section 512 of the act in the definition of ''drug product'' in section 201(dd) of the act. Congress clearly intended the GDEA to ensure the integrity of the animal drug approval process and thereby protect the public health, because the plain language of the GDEA applies to convictions related to animal drugs. Therefore, Mr. Girdhari's argument that application of the GDEA to convictions related to animal drugs would not serve any remedial purpose and, as such, retroactive application of section 306(a)(2) of the act to him would be punitive, is without merit.

C. Retroactive Application of the Statute Violates the Due Process Clause

Mr. Girdhari argues that retroactive application of the GDEA violates the Due Process Clause of the U.S. Constitution. First, Mr. Girdhari relies on *Usery* v. *Turner Elkhorn Mining Co.*, 96 S.Ct. 2882, 2893 (1976), to argue that retroactive application of the GDEA is not justified under the Due Process Clause. Second, Mr. Girdhari argues that the terms of the GDEA as applied to him are overly vague.

1. Usery

Mr. Girdhari argues that even if the GDEA's main purpose is remedial, justification sufficient to support the prospective application of a statute under the Due Process Clause of the Constitution is not always sufficient to justify retrospective application of that statute. Mr. Girdhari cites *Usery* v. *Turner Elkhorn Mining Co.*, 96 S.Ct. 2882, 2893 (1976), in support of this argument. In that case the Court held that the retroactive application of a remedial statute designed to compensate disabled coal miners was not arbitrary and capricious under the Due Process Clause, although the Court noted that it would ''hesitate to approve the retrospective imposition of liability on any theory of deterrence * * * or blameworthiness.'' (Id. (citations omitted).)

Mr. Girdhari's argument is unpersuasive. Mr. Girdhari fails to demonstrate that his debarment is unrelated to any legitimate purpose, or that the retroactive application of the GDEA can only be justified on a theory of deterrence or blameworthiness. As shown above, debarment guards against future violations by prohibiting individuals ''from providing services in any capacity to a person that has an approved or pending drug product application'' in order to meet the legitimate regulatory purpose of restoring the integrity of the drug approval and regulatory process and protecting the public health. Additionally, as shown above, the remedial nature of the GDEA is not diminished simply because the GDEA deters debarred individuals and others from future misconduct. (*U.S.* v. *Halper*, 109 S.Ct. 1892, 1901, n.7 (1989); *Bae* v. *Shalala*, 44 F.3d 489, 493 (7th Cir. 1995).) Thus, the GDEA satisfies the requirements of the Due Process Clause for retroactive application.

2. Vagueness

Mr. Girdhari asserts that the statute's prohibition on providing services ''in any capacity'' is overly vague. The Supreme Court held in *Roberts* v. *United States Jaycees*, 104 S.Ct. 3244, 3256 (1984) (quoting *Connally* v. *General Construction Co.*, 46 S.Ct. 126, 127 (1926)), that ''a statute which either forbids or requires the doing of some act in terms so vague that [persons] of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law.'' The *Roberts* Court explained that the constitutional prohibition against such vague statutes ''enables individuals to conform their conduct to the requirements of the law.'' (*Roberts* at 3256.)

The terms of the debarment order, drawn from the language of the statute,

are sufficiently clear to allow Mr. Girdhari to conform his conduct to the requirements of the law. The court in *DiCola* held that the debarment order's prohibition on services ''in any capacity'' did not render the order unconstitutionally vague under the Due Process Clause of the U.S. Constitution. (*DiCola* at 509.)

The court explained that ''all direct employment by a drug company'' would be within the remedial scope of the debarment order. (*DiCola* at 509.) The court further explained that for employment by enterprises that provided goods or services to a drug company, a debarred individual would ''usually have a pretty good idea whether a position with a firm that is not itself a drug manufacturer runs afoul of the remedial purpose for which he has been debarred* * *'' (*DiCola* at 509.) Finally, the court in *DiCola* noted that a debarred individual could seek a prospective ruling about a specific employment opportunity by filing a citizen petition with the agency. (*DiCola* at 509.) Likewise, if Mr. Girdhari is uncertain whether a specific type of employment would be within the scope of the debarment order, he may file a citizen petition with the agency regarding his inquiry.

D. Application of the Statute Violates the Double Jeopardy Clause

Finally, Mr. Girdhari argues that the proposal to debar him under section 306(a)(2) of the act violates the Double Jeopardy Clause of the Fifth Amendment to the U.S. Constitution. The Double Jeopardy Clause states that no person shall ''be subject for the same offense to be twice put in jeopardy of life or limb.''

Mr. Girdhari argues that the proposed debarment constitutes additional punishment for activities for which he has already been punished. Furthermore, Mr. Girdhari relies on *U.S.* v. *Halper*, 490 U.S. 435 (1989), to argue that permanent debarment is not rationally related to any remedial purpose because such debarment unnecessarily reaches activities that are completely unrelated to drug regulation (e.g., photocopying documents for a drug company).

Mr. Girdhari's arguments are unpersuasive. The Supreme Court in *Hudson* v. *United States*, 118 S.Ct. 488 (1997), in large part disavowed the method of analysis used in *United States* v. *Halper*, 109 S.Ct. 1892 (1989), to determine whether a sanction violates the Double Jeopardy Clause. The Court in *Hudson* held that the Double Jeopardy Clause did not preclude the criminal prosecution for violation of Federal banking statutes of a defendant who had previously been permanently debarred from participating in any banking activities for the same conduct.

The Double Jeopardy Clause protects only against the imposition of multiple criminal punishments for the same offense in successive proceedings. *Hudson* v. *United States*, 118 S.Ct. at 493. The Double Jeopardy Clause does not prohibit the imposition of any additional sanction that could, ''in common parlance,'' be described as punishment. (Id. (internal quotation marks and citations omitted).) The Court in *Hudson* held that whether a particular punishment is criminal or civil is first a matter of statutory construction. (*Hudson* v. *United States*, 118 S.Ct. at 493 (quoting *Helvering* v. *Mitchell*, 58 S.Ct. 630, 633 (1938)).) That is, a court first must ask whether the legislature, ''in establishing the penalizing mechanism, indicated either expressly or impliedly a preference for one label or the other.'' (*Hudson* v. *United States*, 118 S.Ct. at 493 (quoting *United States* v. *Ward*, 100 S.Ct. at 2641).) Second, where the legislature has indicated an intention to establish a civil penalty, a court must inquire further whether the statutory scheme is ''so punitive either in purpose or effect,'' *Hudson* v. *United States*, 118 S.Ct. at 493 (quoting *United States* v. *Ward*, 100 S.Ct. at 2641), as to ''transform what was clearly intended as a civil remedy into a criminal penalty,'' *Hudson* v. *United States*, 118 S.Ct. at 493 (quoting *Rex Trailer Co.* v. *United States*, 76 S.Ct. 219, 222 (1956)).

The debarment of Mr. Girdhari is not a criminal penalty under *Hudson*. First, the legislature in enacting the GDEA intended clearly that debarment serve as a civil penalty. In *Hudson*, the Court found ''it significant that the authority to issue debarment orders is conferred [by statute] upon the appropriate Federal banking agencies','' holding ''[t]hat such [debarment] authority was conferred upon administrative agencies is prima facie evidence that Congress intended to provide for a civil sanction.'' (Id.) Here, the GDEA explicitly provides FDA, through the Secretary of Health and Human Services, with the authority to permanently debar individuals convicted of certain felonies, such as Mr. Girdhari, from ''providing services in any capacity to a person that has an approved or pending drug product application.'' (Section 306(a)(2) of the act.) Thus, under *Hudson*, the terms of the GDEA are prima facie evidence that Congress intended the debarment provisions to be civil in nature.

Under the second prong of *Hudson*, the debarment authorized by the GDEA is not so punitive either in purpose or effect as to transform this civil remedy into a criminal penalty. In *Hudson*, the Court considered whether a permanent debarment sanction prohibiting participation in any banking activities had such a punitive purpose or effect. The Court concluded that there was no evidence to establish that the debarment sanction at issue was ''so punitive in form and effect as to render [it] criminal despite Congress' intent to the contrary.'' (*Hudson* v. *United States*, 118 S.Ct. at 495 (quoting *United States* v. *Ursery*, 116 S.Ct. 2135, 2148 (1996)).) The Court in *Hudson* applied the analysis of *Kennedy* v. *Mendoza–Martinez*, 83 S.Ct. 554, 567–68 (1963), to reaching this holding.

In *Hudson*, the Court first noted that debarment proceedings have not historically been viewed as punishment. (*Hudson* at 495–96.) Second, the Court found that ''[debarment] sanctions do not involve an 'affirmative disability or restraint,' as that term is normally understood.'' (*Hudson* at 496 (quoting *Kennedy*, 83 S.Ct. at 567).) Third, the Court found that the debarment sanction in the banking statute at issue in that case does not ''come into play 'only' on a finding of scienter,'' because willfulness is not a prerequisite to the imposition of the debarment sanction. (Id. (quoting *Kennedy*, 83 S.Ct. at 567).) Likewise, the GDEA does not require a finding of willfulness as a prerequisite to imposing debarment. Fourth, the Court explained that the fact that the conduct for which the debarment is imposed may also be criminal is insufficient to render the debarment sanctions criminally punitive. (Id.) Finally, and significantly, the Court explained that the general deterrence of the conduct at issue resulting from an individual debarment is insufficient to render the debarment criminal. (Id.) These factors apply as much to debarment under the GDEA.

Furthermore, the GDEA's permanent prohibition on services in any capacity to a company with an approved or pending drug product application is not excessive in relation to the statute's remedial purpose. As shown above, both the District of Columbia and the Seventh Circuits have upheld the permanence of the debarment provisions as rationally related to the remedial goals of the statute, (*DiCola* at 507; *Bae* at 495.), and the Supreme Court has upheld similar statutes which, for remedial purposes, impose permanent prohibitions. (See *Hudson* v. *United States*, 118 S.Ct. 488 (1997); *Hawker* v. *New York*, 170 U.S. 189, 190

(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.

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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