Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at respective DOE sites. Activities shall focus on providing a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

Matters to be Discussed: Agenda items include: presentations from the National Center for Environmental Health (NCEH), the National Institute for Occupational Safety and Health, and ATSDR updates on the progress of current studies; discussion of the State oversight program; INEL Dose Evaluation Report; and updates on the technical workshop on ''Calculating and Interpreting Radiological Doses and Risks for Individuals Exposed to Radionuclides Due to Historical Releases from the Hanford Nuclear Reservation'' and a public involvement activities.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Arthur J. Robinson, Jr., or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: February 6, 1996.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 96–5804 Filed 3–8–96; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 94N–0033]

John D. Copanos; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) denies John D. Copanos' request for a hearing and issues a final order under section 306(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 335a(a)) permanently debarring John D. Copanos, 6504 Montrose Ave., Baltimore, MD 21212, from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on its finding that Mr. Copanos was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

EFFECTIVE DATE: March 11, 1996

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., Rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

John D. Copanos was the owner and president of John D. Copanos and Sons, Inc., and Kanasco, Ltd., when, on November 13, 1989, he agreed to plead guilty to one count of distributing misbranded drugs with intent to mislead, a Federal felony offense under sections 301(a) of the act (21 U.S.C. 331(a)) and 303(a)(2)(previously 303(b)) of the act (21 U.S.C. 333(a)(2)) (previously 21 U.S.C. 333(b)), and one count of causing the adulteration of drugs with intent to mislead, a Federal felony offense under sections 301(k) and 303(a)(2) of the act. On February 16, 1990, the United States District Court for the District of Maryland accepted Mr. Copanos' plea of guilty and entered judgment against him for these felonies. The bases for these convictions were as follows.

Mr. Copanos distributed a drug that was misbranded because its labeling failed to bear adequate directions for use and because it failed to warn of the presence of phenylalanine, a component of aspartame. In fact, adequate testing had not been conducted to determine the effect of aspartame on the stability, potency, and effectiveness of this drug. This drug was also misbranded because it failed to reveal the presence and amount of phenylalanine.

In addition, Mr. Copanos pled guilty to causing the adulteration of a drug with intent to mislead by failing to comply with current good manufacturing practice.

In a notice published in the Federal Register of November 9, 1994 (59 FR 55846), FDA offered Mr. Copanos an opportunity for a hearing on the agency's proposal to issue an order under section 306(a) of the act debarring Mr. Copanos from providing services in any capacity to a person that has an approved or pending drug product application. FDA based the proposal to debar Mr. Copanos on its finding that he had been convicted of felonies under Federal law for conduct relating to the regulation of a drug product.

In the Federal Register notice of November 9, 1994, FDA informed Mr. Copanos 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. FDA also informed Mr. Copanos 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 which precluded the order of debarment, FDA would enter summary judgment against him and deny his request for a hearing.

In a letter dated December 8, 1994, Mr. Copanos requested a hearing, and in a letter dated January 6, 1995, Mr. Copanos submitted arguments and information in support of his hearing request. In his request for a hearing, Mr. Copanos does not dispute that he was convicted of a felony under Federal law as alleged by FDA. However, Mr. Copanos argues that: (1) He did not receive proper notice; (2) he is entitled to a hearing to contest or explain the facts underlying his plea; (3) some factual statements in the agency's proposal are inaccurate; (4) the agency's reliance on portions of the indictment is inappropriate; (5) and the agency's proposal to debar him is unconstitutional.

The Deputy Commissioner for Operations has considered Mr. Copanos' 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. Copanos offers do not create the bases for a hearing (see 21 CFR 12.24(b)(1)). Mr. Copanos' arguments are discussed below.

II. Mr. Copanos' Arguments in Support of a Hearing

A. Notice

Mr. Copanos objects to being notified of his proposed debarment through publication in the Federal Register. It is the policy of the agency to send a notice of proposed debarment by certified mail. If certified mail delivery is unsuccessful, the agency attempts to deliver the notice to the individual personally. If this attempt fails also,

notice is given through publication in the Federal Register. FDA attempted to serve Mr. Copanos by certified mail but was unable to do so. In September 1994, FDA's Baltimore District Office learned that Mr. Copanos was out of the country. Agents from FDA's Baltimore District Office visited Mr. Copanos' home weekly to determine if he had returned. FDA's Office of Criminal Investigation arranged with U.S. Customs to be notified if Mr. Copanos returned to the country. When Mr. Copanos did not return to the country, the debarment notice was published in the Federal Register on November 9, 1994.

Mr. Copanos requested a hearing on his proposed debarment and made arguments in support of that request. Thus, it is clear that Mr. Copanos received actual notice of the agency's proposed action and has not been deprived of any procedural rights by virtue of publication of the debarment notice in the Federal Register.

B. Facts Underlying the Plea

Mr. Copanos makes the following statements relating to the facts underlying his plea. He states that he held a management position and did not personally misbrand or manufacture adulterated drugs, that none of the drugs or products involved were put into commerce, and that the first count of the plea related to a facility that was not under his full control at the time. Mr. Copanos also states that the agency's proposal sets forth areas of indictment information and factual statements of allegations rather than actual proof.

Mr. Copanos is correct that the agency's proposal contained some inaccuracies. Although Mr. Copanos pled guilty to counts four and six of the indictment against him, he did not plead guilty to all the particulars listed in the indictment. In its debarment proposal, the agency mistakenly referred to parts of the indictment to which Mr. Copanos did not plead. The agency very much regrets this error. However, this misplaced reliance does not raise a genuine and substantial issue of fact requiring a hearing.

The act requires FDA to mandatorily debar an individual who has been convicted of certain Federal felonies. The only relevant factual issue is whether Mr. Copanos was, in fact, convicted. Mr. Copanos does not dispute that he pled guilty to two Federal felony counts for actions that relate to the regulation of a drug product. Section 306(l) of the act includes in its definition of a conviction, a guilty plea. Accordingly, Mr. Copanos' statements regarding the factual circumstances underlying his plea fail to raise a genuine and substantial issue of fact justifying a hearing.

C. Ex Post Facto Argument

Mr. Copanos argues that the ex post facto clause of the U.S. Constitution prohibits application of section 306(a)(2) of the act to him because this section was not in effect at the time of Mr. Copanos' criminal conduct. The Generic Drug Enforcement Act (GDEA) of 1992, including section 306(a)(2), was enacted on May 13, 1992, and Mr. Copanos was convicted on February 16, 1990.

An ex post facto law is one that reaches back to punish acts that occurred before enactment of the law or that adds a new punishment to one that was in effect when the crime was committed. (*Ex Parte Garland*, 4 Wall. 333, 377, 18 L. Ed. 366 (1866); *Collins* v. *Youngblood*, 497 U.S. 37 (1990).)

Mr. Copanos' claim that application of the mandatory debarment provisions of the act is prohibited by the ex post facto clause is unpersuasive, because the intent of debarment is remedial, not punitive. Congress created the GDEA in response to findings of fraud and corruption in the generic drug industry. Both the language of the GDEA and its legislative history reveal that the purpose of the debarment provisions set forth in the GDEA is ''to restore and ensure the integrity of the abbreviated new drug application (ANDA) approval process and to protect the public health.'' (See section 1, Pub. L. 102–282, GDEA of 1992.)

In a suit challenging a debarment order issued by FDA (58 FR 69368, December 30, 1993), the constitutionality of the debarment provision was upheld against a similar challenge under the ex post facto clause. The reviewing court affirmed the remedial character of debarment:

> Without question, the GDEA serves compelling governmental interests unrelated to punishment. 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 v. *Shalala*, 44 F.3d 489, 493 (7th Cir. 1995). Because the intent of the GDEA is remedial rather than punitive, Mr. Copanos' argument that the GDEA violates the ex post facto clause must fail. *See id*. at 496–97.

D. Miscellaneous Arguments

Mr. Copanos argues that his debarment would be ''an unconstitutional taking of the right to earn a living in the United States.'' It appears that Mr. Copanos is referring to a ''taking'' of property under the Fifth Amendment. Mr. Copanos further states that he has sold his company, including all of its approved applications, and that to debar him now ''1would be a malicious act'' on the part of the agency. Mr. Copanos also argues that he should not be debarred because his guilty plea was made at an emotional and stressful time.

None of these arguments raise a genuine and substantial issue of fact requiring resolution at a hearing. Mr. Copanos has not established that his debarment affects any property interest protected by the Fifth Amendment. The expectation of employment is not recognized as a protected property interest under the Fifth Amendment. *Hoopa Valley Tribe* v. *Christie*, 812 F.2d 1097, 1102 (9th Cir. 1986); *Chang* v. *United States*, 859 F.2d 893, 896–97 (Fed. Cir. 1988). Loss of potential profit is not a sufficient basis for a ''takings'' claim. *Andrus* v. *Allard*, 444 U.S. 51, 66 (1979). To have a protected property interest, one must have a ''legitimate claim of entitlement'' to that interest. *Erikson* v. *United States*, 67 F.3d 858 (9th Cir. 1995). One who voluntarily enters a pervasively regulated industry, such as the pharmaceutical industry, and then violates its regulations, cannot successfully claim that he has a protected property interest when he is no longer entitled to the benefits of that industry. *Id*.

Mr. Copanos does not dispute that he was convicted as alleged by FDA. Under section 306(l)(1)(B) of the act a conviction includes a guilty plea. The facts underlying Mr. Copanos' conviction are not at issue. Moreover, the act does not permit consideration of factors such as emotional stress; rather, the act is clear that an individual shall be debarred if convicted of a felony under Federal law for conduct relating to the regulation of any drug product (see section 306(a)(2)(B) of the act). Mr. Copanos has been convicted of such a felony. Accordingly, the Deputy Commissioner for Operations denies Mr. Copanos' request for a hearing.

III. Findings and Order

Therefore, the Deputy Commissioner for Operations, under section 306(a) of the act and under authority delegated to him (21 CFR 5.20), finds that John D. Copanos has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product (21 U.S.C. 335a(a)(2)(B)).

As a result of the foregoing findings, John D. Copanos is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application

under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (*insert date of publication in the* Federal Register), (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Copanos, in any capacity, during his period of debarment, will be subject to a civil money penalty (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Copanos, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to a civil penalty (section 307(a)(7) of the act). In addition, FDA will not accept or review any ANDA or abbreviated antibiotic drug application submitted by or with Mr. Copanos' assistance during his period of debarment.

Mr. Copanos may file an application to attempt to terminate his debarment pursuant to 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–0033 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 between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 22, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–5687 Filed 3–8–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: March 19, 1996.

Time: 1 p.m.

Place: Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Jean G. Noronha, Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–6470.

This notice is being published less than fifteen days prior to the above meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: March 26, 1996.

Time: 3 p.m.

Place: Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Jean G. Noronha, Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–6470.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: March 27, 1996.

Time: 3 p.m.

Place: Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Jean G. Noronha, Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–6470.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: March 5, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–5667 Filed 3–8–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: March 14, 1996.

Time: 10 a.m.

Place: Days Inn, 2000 Jefferson Davis Hwy., Crystal City, VA 22202.

Contact Person: Angela L. Redlingshafer, Parklawn, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1367.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282).

Dated: March 5, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

FR Doc. 96–5668 Filed 3–8–96; 8:45 am]

BILLING CODE 4140–01–M

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Behavioral and Neurosciences.

Date: March 19, 1996.

Time: 12:00 p.m.

Place: Ramada Inn, Rockville, Maryland.

Contact Person: Dr. Joseph Kimm, Scientific Review Administrator, 6701 Rockledge Drive, Room 5178, Bethesda, Maryland 20892, (301) 435–1249.

Name of SEP: Microbiological and Immunological Sciences.

Date: March 25, 1996.

Time: 10:00 a.m.

Place: NIH, Rockledge 2, Room 4184, Telephone Conference.

Contact Person: Dr. Martin Slater, Scientific Review Administrator, 6701 Rockledge Drive, Room 4184, Bethesda, Maryland 20892, (301) 435–1149.

Name of SEP: Microbiological and Immunological Sciences.

Date: March 26, 1996.

Time: 1:30 p.m.

Place: NIH, Rockledge 2, Room 4182, Telephone Conference.

Contact Person: Dr. William Branche, Jr., Scientific Review Administrator, 6701 Rockledge Drive, Room 4182, Bethesda, Maryland 20892, (301) 435–1148.

Name of SEP: Biological and Physiological Sciences.

Date: March 26, 1996.

Time: 8:30 a.m.

Place: NIH, Rockledge 2, Conf. Room 9116.

Contact Person: Dr. Sooja Kim, Scientific Review Administrator, 6701 Rockledge Drive, Room 4120, Bethesda, Maryland 20892, (301) 435–1780.

Name of SEP: Microbiological and Immunological Sciences.