detection of a problem or complaints from product users or their veterinarians using forms FDA Forms 1932 and 1932a. Form FDA 2301 is available for the required transmittal of periodic reports and promotional material for new animal drugs. Respondents to this collection of information are applicants of approved NADA's.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 2301	510.302(a)	190	19.74	3,750	0.5	1875
FDA 1932	510.302(b)	190	15.26	2,900	1.0	290
FDA 1932a (voluntary)	510.302(b)	100	1.0	100	1.0	100
Total Burden Hours						4,875

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.300(a) and 510.301(a)	190	15.26	3,750	10.35	38,812
510.300(b) and 510.301(b)	190	19.74	2,900	0.50	1,450
Total Burden Hours					40,262

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the times required for record preparation and maintenance is based on agency communication with industry. Other information needed to calculate the total burden hours (i.e., adverse drug reaction, lack of effectiveness, and product defect reports) are derived from agency records and experience.

Dated: June 3, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15485 Filed 6–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0131]

Scott Feuer; Final 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 act) debarring Scott Feuer, 25 Glenwood Rd., Tenafly, NJ 07670, for a period of 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on finding that Mr. Feuer was convicted of conspiracy to commit an offense against the United States and that Mr. Feuer's conduct undermined the process for the regulation of drugs. Mr. Feuer has failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

EFFECTIVE DATE: June 2, 1998.

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: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On March 24, 1993, the United States District Court for the District of Maryland accepted Mr. Feuer's plea of guilty to one count of conspiracy to commit an offense against the United States under 18 U.S.C. 371 and 18 U.S.C. 2. This conspiracy conviction was based on Mr. Feuer's directing others to change manufacturing procedures for the generic drug Fenoprophen, falsifying records in order to conceal from the FDA the manufacturing changes, and distributing the Fenoprophen without FDA approval of the formula actually distributed.

As a result of this conviction, FDA served Mr. Feuer by certified mail on March 2, 1998, a notice proposing to debar him for a period of 5 years from providing services in any capacity to a person that has an approved or pending drug product application, and offered him an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Mr. Feuer was convicted of a conspiracy to commit a felony under Federal law for conduct relating to the regulation of a drug product and that Mr. Feuer's conduct undermined the process for the regulation of drugs. Mr. Feuer did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director of the Center for Drug Evaluation and Research, under section 306(b) of the act, and under authority delegated to her (21 CFR 5.99(b)), finds that Scott Feuer has been convicted of conspiracy to commit a felony under Federal law for conduct relating to the regulation of a drug product and that Mr. Feur's conduct undermined the process for the regulation of drugs.

As a result of the foregoing finding, Scott Feuer is 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 June 2, 1998 (sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))), for a

period of 5 years. Any person with an approved or pending drug product application who knowingly uses the services of Mr. Feuer in any in any capacity during his period of debarment will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Feuer, 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 civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications or abbreviated antibiotic drug applications submitted by or with the assistance of Mr. Feuer during his period of debarment.

Any application by Mr. Feuer for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 98N–0131 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: May 18, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98–15482 Filed 6–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0299]

International Conference on Harmonisation; Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guidance entitled ''E5 Ethnic Factors in the Acceptability of Foreign Clinical Data.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance recommends regulatory and development strategies to permit clinical data collected in one region to be used for the support of drug and biologic registrations in another region while allowing for the influence of ethnic factors.

DATES: Effective June 10, 1998. Submit written comments at any time.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Single copies of the guidance may be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Copies may be obtained from CBER's FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Barbara G. Matthews, Center for Biologics Evaluation and Research (HFM–570), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5094.

Regarding ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the **Federal Register** of July 31, 1997 (62 FR 41054), FDA published a draft tripartite guideline entitled ''Ethnic Factors in the Acceptability of Foreign Clinical Data'' (E5). The notice gave interested persons an opportunity to submit comments by October 29, 1997.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on February 5, 1998.

In accordance with FDA's good guidance practices (62 FR 8961, February 27, 1997), this document has been designated a guidance, rather than a guideline.

The guidance is intended to facilitate the registration of drugs and biologics among ICH regions by recommending a framework for evaluating the impact of ethnic factors on a drug's effect, i.e., its efficacy and safety at a particular dosage and dose regimen. The guidance recommends regulatory and development strategies that will permit adequate evaluation of the influence of ethnic factors, minimize duplication of clinical studies, and expedite the drug approval process.

This guidance represents the agency's current thinking on ethnic factors in the acceptability of foreign clinical data for approval of both drugs and biologics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. The comments in the docket will be