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
58.29(b)	400	20	8,000	.21	1,700
58.35(b)(1) through (b)(6) and (c)	400	270.76	108,400	3.36	363,900
58.63(b) and (c)	400	60	24,000	.09	2,200
58.81(a) through (c)	400	301.8	120,000	.14	16,800
58.90(c) and (g)	400	62.7	25,000	.13	3,200
58.105(a) and (b)	400	5	2,000	11.8	23,600
58.107(d)	400	1	400	4.25	1,700
58.113(a)	400	15.33	6,132	6.8	41,700
58.120	400	15.38	6,160	32.7	201,200
58.195	400	251.5	100,000	3.9	392,400
Total					1,048,400

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

Dated: June 3, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15409 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–0308]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements obligating holders of approved new animal drug applications (NADA's) and abbreviated new animal drug applications to submit information on adverse drug reactions, lack of effectiveness and product defects.

DATES: Submit written comments on the collection of information by August 10, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report—21 CFR Part 510—(OMB Control Number 0910–0012—Reinstatement)

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)), 21 CFR 510.300, 510.301, and 510.302 require that applicants of approved NADA's submit within 15 working days of receipt, complete records of reports of certain adverse drug reactions and unusual failure of new animal drugs. Other reporting requirements of adverse reactions to these drugs must be reported annually or semiannually in a specific format.

This continuous monitoring of approved new animal drugs, affords the primary means by which FDA obtains information regarding potential problems in safety and effectiveness of marketed animal drugs and potential manufacturing problems. Data already on file with FDA is not adequate because animal drug effects can change over time and less apparent effects may take years to manifest themselves. Reports are reviewed along with those previously submitted for a particular drug to determine if any change is needed in the product or labeling, such as package insert changes, dosage changes, additional warnings or contraindications, or product reformulation.

Adverse reaction reports are required to be submitted by the drug manufacturer on FDA Forms 1932 or 1932a (voluntary reporting form), following complaints from animal owners or veterinarians. Also, product defects and lack of effectiveness complaints are submitted to FDA by the drug manufacturer following their own

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