

Short title	16 CFR	OMB Control No.
Wool Act Regulations .....	Part 300 .....	3084-0100
Fur Act Regulations .....	Part 301 .....	3084-0099
Textile Act Regulations .....	Part 303 .....	3084-0101
Appliance Labeling Rule .....	Part 305 .....	3084-0069
Fuel Rating Rule .....	Part 306 .....	3084-0068
Smokeless Tobacco Rule .....	Part 307 .....	3084-0082
900 Number Rule .....	Part 308 .....	3084-0102
Alternative Fuel Rule .....	Part 309 .....	3084-0094
Telemarketing Rule .....	Part 310 .....	3084-0097
Games of Chance Rule .....	Part 419 .....	3084-0067
Care Labeling Rule .....	Part 423 .....	3084-0103
Negative Option Plans Rule .....	Part 425 .....	3084-0104
Amplifier Rule .....	Part 432 .....	3084-0105
Mail Order Rule .....	Part 435 .....	3084-0106
Franchise Rule .....	Part 436 .....	3084-0107
Funeral Rule .....	Part 453 .....	3084-0025
Used Car Rule .....	Part 455 .....	3084-0108
R-Value Rule (Home Insulation) .....	Part 460 .....	3084-0109
Fair Packaging and Labeling Act Regulations .....	Part 500 .....	3084-0110
Consumer Product Warranty Rule .....	Part 701 .....	3084-0111
Pre-Sale Availability Rule .....	Part 702 .....	3084-0112
Informal Dispute Settlement Rule .....	Part 703 .....	3084-0113
Rules under the Hart-Scott-Rodino Act .....	Part 801-803 .....	3084-0005
FTC Administrative and Procurement Activities .....	Part Parts 1, II, and IV, Part III, Subpart I, Part 901, FTC Form 14.	3084-0047

By direction of the Commission.  
[FR Doc. 96-4561 Filed 2-27-96; 8:45 am]  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 95N-0280]

#### Fredrick Jay Shainfeld; 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) permanently debaring Dr. Fredrick Shainfeld 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 Dr. Shainfeld was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product; and relating to the regulation of a drug product under the act. Dr. Shainfeld has notified FDA that he acquiesces to debarment and, therefore, has waived his opportunity for a hearing concerning this action.

**EFFECTIVE DATE:** March 10, 1995.

**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:**

Tamar S. Nordenberg, 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**

Dr. Fredrick Shainfeld, a former senior vice president of Technical and Regulatory Affairs and New Product Development at Halsey Drug Co. (Halsey), was sentenced on January 6, 1995, pursuant to a guilty plea, for obstruction of an agency proceeding, a Federal felony under 18 U.S.C. 1505. The basis for this conviction was as follows:

Dr. Shainfeld, in his capacity as senior vice president for Technical and Regulatory Affairs and New Product Development, supervised Halsey's regulatory filings to FDA. During a 1989 FDA establishment inspection of Halsey, Dr. Shainfeld and other members of Halsey's upper management provided FDA inspectors with a falsified raw material inventory card for Fenoprofen Calcium.

Dr. Shainfeld knew that the raw material card falsely stated that Halsey had received 50 kilograms of

Fenoprofen Calcium on September 11, 1987, when in fact Halsey had received half that amount, and Dr. Shainfeld knew that the purpose of the falsification was to conceal from FDA that Halsey did not have enough raw material to manufacture its pilot batches in the sizes represented in abbreviated new drug applications (ANDA's) for the generic drug product Fenoprofen Calcium.

Dr. Shainfeld is subject to debarment based on a finding, under section 306(a)(2) of the act (21 U.S.C. 335a(a)(2)), that he was convicted of a felony under Federal law for conduct relating to the development, approval, and regulation of a drug product.

The purpose of the falsification of the raw material inventory cards for Fenoprofen Calcium was to conceal from FDA the fact that Halsey did not have enough raw material to manufacture its pilot batches in the sizes represented in the product's ANDA's. The falsification relates to the development or approval of a drug product because FDA makes its decisions whether to approve a product based on the information in the ANDA's. If the pilot batches were not manufactured in the sizes represented in the ANDA's, FDA made its approval decisions based on erroneous information.

The falsification of the raw material inventory cards relates to the regulation of drug products because FDA's regulatory decisions about Halsey drug

products may have been affected by the conduct.

In a letter received by FDA on March 10, 1995, Dr. Shainfeld notified FDA of his acquiescence to debarment, as provided for in section 306(c)(2)(B) of the act. A person subject to debarment is entitled to an opportunity for an agency hearing on disputed issues of material fact under section 306(i) of the act, but by acquiescing to debarment, Dr. Shainfeld waived his opportunity for a hearing and any contentions concerning his debarment.

## II. 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 Dr. Fredrick Shainfeld 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 (21 U.S.C. 335a(a)(2)(A)); and (2) relating to the regulation of a drug product (21 U.S.C. 335a(a)(2)(B)).

As a result of the foregoing findings and based on his notification of acquiescence, Dr. Fredrick Shainfeld 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 March 10, 1995, the date of notification of acquiescence (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Dr. Shainfeld, in any capacity, during his period of debarment, will be subject to civil money penalties. If Dr. Shainfeld, 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. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Shainfeld during his period of debarment.

Any application by Dr. Shainfeld for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 95N-0280 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 8, 1996.  
Michael A. Friedman,  
*Deputy Commissioner for Operations.*  
[FR Doc. 96-4473 Filed 2-27-96; 8:45 am]  
BILLING CODE 4160-01-F

## Health Care Financing Administration

### Public Information Collection Requirements Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Medicare and Medicaid Disclosure of Ownership and Control Interest Statement; *Form No.:* HCFA-1513; *Use:* The information provided on this form is used by State agencies and HCFA regional offices to determine whether providers meet the eligibility requirements for Titles 18 and 19 (Medicare and Medicaid) and for grants under Titles 5 and 20. Review of ownership and control is particularly necessary to prohibit ownership and control for individuals excluded under Federal Fraud statutes; *Frequency:* On Occasion; *Affected Public:* Business or other for profit, not-for-profit; *Number of Respondents:* 60,000; *Total Annual Hours:* 30,000.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Evaluation of the Program of All-Inclusive Care for the Elderly (PACE) Demonstration; *Form No.:* HCFA-R-165; *Use:* This survey will

collect data on functional status, service utility, and out-of-pocket costs, and satisfaction for a sample of applicants to the PACE program. This information will be to analyze the decision to participate in PACE and the impact of the program; *Frequency:* Semi-annually; *Affected Public:* Individuals and households; *Number of Respondents:* 1,833; *Total Annual Hours:* 3,745.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.ssa.gov/hcfa/hcfahp2.html>, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: John Burke, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 16, 1996.  
Kathleen B. Larson,  
*Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.*  
[FR Doc. 96-4534 Filed 2-27-96; 8:45 am]  
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## Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including