SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 97–22861 Filed 8–27–97; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0496]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by September 29, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Judith V. Bigelow, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1479.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

Reporting and Recordkeeping Requirements for Manufacturers and Distributors of Electronic Products—21 CFR Parts 1002–1010, FDA Forms 2877, 3147, and 766 (OMB Control Number 0910–0025—Reinstatement)

Sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ii through 360ss) direct the Secretary of the Department of Health and Human Services (the Secretary) to establish and carry out an electronic product radiation control program to protect the public from unnecessary radiation from electronic products. Such program shall include the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. Section 534(g) of the act (21 U.S.C. 360kk(g)) directs the Secretary to review and evaluate industry testing programs on a continuing basis, and section 535(e) and (f) of the act (21 U.S.C. 360*ll*(e) and (f)) directs the Secretary to immediately notify manufacturers of, and assure correction of, radiation defects or noncompliances with performance standards. The authority for records and reports is contained in section 537(b) and (c) of the act (21 U.S.C. 360nn(b) and (c)).

The regulations implementing these statutory provisions are found in parts 1002 through 1010 (21 CFR parts 1002 through 1010). Section 1002.3 requires manufacturers, when directed by FDA, to provide technical and safety information to users. Section 1002.10(a) through (k) requires manufacturers to submit to FDA product reports containing identification, design, operation and testing, quality control procedures, test results, and product labeling prior to the entry of the product into commerce. Section 1002.11(a) and (b) requires manufacturers to submit supplemental reports to FDA if modifications in product safety or testing of electronic products affect actual or potential radiation emission. Section 1002.12(a) through (e) requires manufacturers to submit abbreviated information on product safety and testing. Section 1002.13(a) through (c) requires manufacturers to report annually to FDA a summary of manufacturer records maintained in accordance with § 1002.30, and provide quarterly updates of models instead of § 1002.10 or § 1002.11 reports. Section 1002.20(a) through (c) requires manufacturers to report to FDA the circumstances, amount of exposure, and remedial actions taken concerning any accidental radiation occurrence involving their electronic products. If a firm is also required to report the incident under 21 CFR part 803, those regulations take precedence. Section 1002.30(a) and (b) requires manufacturers to keep records on test data and procedures, correspondence regarding radiation safety, and distribution records. Section 1002.31(a) requires manufacturers to maintain records required to be kept under part 1002 for 5 years. Section 1002.31(c) requires manufacturers, when requested by FDA, to provide copies of the distribution records required to be maintained by § 1002.30(b). Section 1002.40(a) through (c) requires dealers and distributors to retain first purchaser information, to be used by manufacturers when a product recall is instituted to ensure the radiation safety of a product. Section 1002.41(a) and (b) specifies that the dealer/distributor records in § 1002.40 may be retained by the dealer or forwarded to the manufacturer for retention and that the manufacturer or dealer shall retain distribution records for 5 years. Section 1002.50(a) specifies criteria by which manufacturers may request exemption from reporting and recordkeeping requirements when there is a low risk of injury, and § 1002.51 specifies criteria by which manufacturers may request exemption from reporting and recordkeeping requirements under certain circumstances if the product is intended for U.S. Government use. The burden is combined with § 1002.50(a), because the processes and procedures are identical.

Section 1003.10(a) and (c) requires manufacturers to notify FDA when their product has a defect or fails to comply with applicable performance standards. Also, under § 1003.10(b) manufacturers must notify purchasers, dealers, and distributors of product defects or noncompliance. Section 1003.11(a)(3) specifies criteria by which manufacturers may refute FDA's notice of defective or noncompliant product, and § 1003.11(b) states that manufacturers, when notified by FDA, must provide information on the number of defective products introduced into commerce. Section 1003.20(a) through (h) specifies information to be provided by manufacturers to FDA when the manufacturer discovers a defect or failure to comply. Section 1003.21(a) through (d) specifies the content and format of the notification by manufacturers to affected persons required by § 1003.10(a). Under § 1003.22(a) and (b), manufacturers must provide to FDA copies of the § 1003.10 disclosure sent to purchasers and to dealers or distributors. Section 1003.30(a) and (b) specifies criteria by which manufacturers may request an exemption from the § 1003.10 disclosure and possible product recall and § 1003.31(a) and (b) specifies the content of the § 1003.30 report and the procedure that the agency will follow in reviewing exemption requests. Sections 1004.2(a) through (i), 1004.3(a) through (i), and 1004.4(a) through (h) require manufacturers to report to FDA every plan to remedy a product defect or noncompliance through repair or replacement or refund.

Section 1005.21(a) through (c) specifies criteria for manufacturers or importers to request correction of noncompliant products for importation into the United States, including specific corrections, timeframe, and location for completion. Such requests are made on Form FDA 766, Application for Authorization to Relabel or to perform other action of the act and other related acts. Section 1005.25(a) and (b) requires importers to report identification information and compliance status of products to FDA. Initial designations are provided in the §§ 1002.10, 1002.11, and 1002.12 reports, so that burden is included in those sections. For each shipment, identification is made on Form FDA 2877. Form FDA 2877, Declaration for Products Subject to Radiation Control Standards, is used to collect this information.

Part 1010 prescribes performance standards for electronic products, under section 534 of the act, to which manufacturers must certify. Section 1010.2(d) specifies criteria for manufacturers to request alternate means of certification to a performance standard. Section 1010.3(a) through (c) requires manufacturers to provide to FDA the coding systems if information on labels is coded and to identify each brand name, and the name and address of the individual or company for whom each product so branded is manufactured. Because firms provide such information in the §§ 1002.10, 1002.11, and 1002.12 reports, the burden is included in those sections. Section 1010.4(b) specifies criteria for manufacturers to petition FDA for a variance from a performance standard. Form FDA 3147, Application for a Variance from 21 CFR 1040.11(c) for laser light shows, is used only by manufacturers of laser products to submit the information. Since the vast majority of variances are submitted by this industry, this form was developed to reduce the burden and timeframe for approvals. Section 1010.5(c) and (d) specifies criteria by which manufacturers or U.S. Government agencies may request an exemption (or amendment or extension) from performance standards when a product is to be used exclusively by a part of the U.S. Government and has adequate radiation emission specifications. Section 1010.13 provides that manufacturers may request alternate test procedures from those specified in a performance standard. The burden is combined with § 1010.5(c) and (d) because the processes and procedures are identical.

The information collections are placed upon manufacturers, importers, assemblers, distributors, and dealers of electronic products. Not all of the requirements are placed on all of these groups. The data reported to FDA and the records that are maintained are used by FDA and the industry to make decisions and take actions that protect the public from radiation hazards presented by electronic products. The reports are reviewed by FDA staff to determine product safety and adequacy of quality control testing. Potential and actual problems are resolved with the individual firm. Each firm's quality control staff reviews the test records to maintain production of safe and compliant products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

If FDA did not collect this information, FDA may not have sufficient information to take appropriate actions to protect the public from unnecessary radiation hazards presented by electronic products.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating and Maintenance Costs
1002.3	10	1	10	12	120	$2,940
1002.10, 1010.3	540	1.6	850	24	20,400	$499,800
1002.11	1,000	1.5	1,500	0.5	750	$18,375
1002.12	150	1	150	5	750	$18,375
1002.13 Annual	900	1	900	26	23,400	$573,300
1002.13 Quarterly	250	2.4	600	0.5	300	$7,350
1002.20	40	1	40	2	80	$1,960
1002.50(a), 1002.51	10	1.5	15	1	15	$367.50
Form FDA 2877	600	32	19,200	0.2	3,840	$94,080
1010.2	1	1	1	5	5	$122.50
1010.4 and Form FDA 3147	53	2.1	115	0.5	58	$1,421
1010.4—Other	1	1	1	120	120	$2,940
1010.5, 1010.13	3	1	3	22	66	$1,617
Totals	1,760		23,385		49,904	$1,222,648

There are no capital costs associated with this collection.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating and Maintenance Costs
1002.30, 1002.31(a)	1,150	1,655.5	1,903,825	198.7	228,505	$5,598,373
1002.40, 1002.41	2,950	49.2	145,140	2.4	7,080	$173,460
Totals	4,100				235,585	

There are no capital costs associated with this collection.

These burden estimates are based on comments from industry and interviews with industry personnel.

Several requirements are not included in the burden chart because they are exempt under 5 CFR 1320.4. These exempt requirements are: Sections 1002.31(c), 1003.10(a) through (c), 1003.11(a)(3), 1003.11(b), 1003.20(a)

through (h), 1003.21(a) through (d), 1003.22(a) and (b), 1003.30(a) and (b), 1003.31(a) and (b), 1004.2(a) through (i), 1004.3(a) through (i), 1004.4(a) through (h) and 1005.21(a) through (c). Other requirements are not included because they constitute a disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)).

Dated: August 20, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22857 Filed 8–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0221]

Benzodiazepines and Related Substances; Criteria for Scheduling Recommendations Under the Controlled Substance Act; Notice of Public Hearing Modification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) in conjunction with other Federal agencies is announcing that the part 15 public hearing on benzodiazepines and related substances originally scheduled for September 11 and 12, 1997, will be held only on September 11, 1997. The public hearing will not continue to September 12, 1997. The decision to forego the second day is based on the limited number of respondents submitting notices of participation in the hearing.

DATES: The hearing will be held on Thursday September 11, 1997, from 9 a.m. to 4 p.m. The closing date for comments will be October 17, 1997.

ADDRESSES: The public hearing will be held at the Renaissance Hotel, 999 Ninth St. NW., Washington, DC. Comments are to be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Transcripts of the public hearing may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the hearing, at a cost of 10 cents per page. The transcript of the public hearing, copies of data and information submitted during the hearing, and any written comments will be available for review at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Nicholas P. Reuter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, rm. 15–22, Rockville, MD 20857, 301–827–1696, FAX 301–443– 0232, e-mail ''nreuter@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

In a notice published in the Federal Register of June 19, 1997 (62 FR 33418), FDA in conjunction with other Federal agencies announced that it would convene a part 15 public hearing on benzodiazepines and related substances. The public hearing was scheduled for Thursday, September 11, 1997 and part of Friday, September 12, 1997.

Persons who wished to participate in the hearing were asked to file a notice of participation with the Dockets Management Branch (address above) on or before August 14, 1997. In response to that notice, eight individuals representing various organizations indicated their interest in participating in the hearing. FDA, along with the other participating agencies, have determined that the number of individuals indicating an interest in participating in the hearing can be accommodated in one full day and that there is no need to continue the hearing to the second day. Therefore, the public hearing will be held at the address above from approximately 9 a.m. until 4 p.m. on September 11, 1997.

Interested parties may still sign up to participate in the hearing. The June 19, 1997, notice included a provision whereby persons may give oral notice of participation by calling Nicholas Reuter (telephone number above) no later than August 29, 1997. This notice extends until September 3, 1997, the opportunity to give oral notice of participation. Those persons who give oral notice of participation should also submit written notice containing the information described above to the Dockets Management Branch by the close of business September 8, 1997.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22935 Filed 8–25–97; 11:56 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0256]

Norma D. Banks; 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 debarring Norma D. Banks, 3688 West Minarets Ave., Fresno, CA 91331, 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 Ms. Banks was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Ms. Banks has failed to request a hearing and, therefore, has waived her opportunity for a hearing concerning this action.

EFFECTIVE DATE: August 28, 1997.

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

Ms. Banks was employed by H. R. Cenci Laboratories, Inc. (Cenci), as Director of Quality Assurance and Regulatory Affairs. In that capacity, on November 17, 1993, she knowingly and willfully made false, fictitious, and fraudulent representations in a matter within the jurisdiction of FDA. Specifically, she misrepresented to FDA's Office of Generic Drugs information contained in an annual report that stability tests for three drug products manufactured by H. R. Cenci Laboratories, Inc. (i.e., promethazine syrup with phenylephrine, promethazine syrup with codeine, and promethazine syrup with phenylephrine and codeine), were uniformly passing, when, in fact, several stability test results were failing.

On January 25, 1996, the United States District Court for the District of Maryland entered judgment against Ms.