grantee agencies and will continue to be used for (1) research, (2) federal monitoring, and (3) internal project management.

Respondents: Not-for-profit institutions; Individuals or Households; and State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Recruitment	566	1	.25	142
New family profile	566	1	.50	283
Updated family profile	2,460	1	.17	418
Development screening/assessment	4,846	.25	.25	1,212
Family needs assessment	2,460	2	.50	2,460
Family service plan	2,460	2	.25	1,230
Contact summary	2,460	50	.12	14,760
Rehabilitative services	8,069	4	.12	3,873
Pregnancy description	418	1	.25	105

Estimated total annual burden hours: 24,483.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: January 15, 1997.

Douglas O. Godesky,

Reports Clearance Officer.

[FR Doc. 97–1497 Filed 1–21–97; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 96N–0454]

Agency Information Collection Activities: Proposed Collections; Comment Request; Reinstatements

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 a 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 provisions related to investigational device exemptions (IDE) reports and records; requirements for premarket notifications and summaries filed under the Federal Food, Drug, and Cosmetic Act (the act); and reporting and recordkeeping requirements imposed on entities that have had products detained during an establishment inspection that are believed to be adulterated or misbranded, or have had products banned.

DATES: Submit written comments on the collections of information by March 24, 1997.

ADDRESSES: Submit written comments on the collections 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: 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: 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 of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collections of information listed below.

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

1. Investigational Device Exemptions Reports and Records (Part 812 (21 CFR Part 812)) (OMB Control Number 0910–0078—Reinstatement)

This information is collected under the statutory authority of the act regarding investigational devices (section 520(g) (21 U.S.C. 360j(g))). An IDE allows a device, which would otherwise be subject to provisions of the act such as premarket notification or premarket approval, to be used in

investigations involving human subjects in which the safety and effectiveness of the device is being studied. The purpose of this section, as explained in § 812.1, is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use. Under §§ 812.20, 812.25, and 812.27, information collected in the application includes sponsor information; a report of prior investigations including reports of all prior clinical, animal, and laboratory testing of the device, a bibliography of all publications, and a summary of all other unpublished information; an investigational plan including study, purpose, protocol, risk analysis, device description, and monitoring procedures; a description of the methods, facilities, and controls used for the manufacture, processing, packing, and storage of the device; investigator information including agreements and certifications; institutional review board (IRB) information; information on the amount to be charged for the device; device labeling; and informed consent materials.

Section 812.10 (waiver of IDE requirements) states that if a sponsor does not wish to comply with certain requirements of part 812, the sponsor may voluntarily submit a waiver request.

Under § 812.35, when an investigational plan changes, a sponsor is required to submit a supplemental application to FDA, and the sponsor may not begin a part of an investigation at a facility until the IRB has approved the investigation, FDA has received the certification of IRB approval, and FDA has approved the supplemental application relating to that part of the investigation.

Section 812.140 requires investigators to maintain records, including correspondence and reports concerning the study; records of receipt, use or disposition of devices; records of each subject's case history and exposure to the device; informed consent documentation; study protocol and documentation of any deviation from the protocol. Sponsors are required, under the same section, to maintain records including correspondence and reports concerning the study; records of shipment and disposition; signed investigator agreements; adverse device effects information; and, if of nonsignificant risk, an explanation of nonsignificant risk determination, records on device name and intended use, study objectives, investigator information, IRB information, and statement on the extent that good manufacturing practices will be followed.

Section 812.150 requires investigators to submit reports on unanticipated adverse device effects, withdrawal of IRB approval, progress reports, deviations from investigational plan, failure to obtain informed consent, and final report. Sponsors are required to submit reports on unanticipated adverse device effects, withdrawal of IRB approval, withdrawal of FDA approval, current investigator lists, progress reports, notification of recall and device disposition, final report, failure to obtain informed consent, and significant risk device determination.

The following parts of the IDE regulations are covered by other sections of part 812, and thus are not mentioned as separate reporting or recordkeeping burden requirements. The requirements for § 812.18 (import and export requirements for IDE's) are already covered under § 812.20(b)(1). Section 812.18 states that foreign companies are required to be sponsored by a U.S. agent, whose identity is required under the IDE application. This is not an additional information collection, and a separate requirement for information is not essential just because this is an imported device. Sections 812.40, 812.45, and 812.46, regarding the general responsibilities of sponsors, are described under §§ 812.20 (actual application) and 812.150 (recordkeeping).

Section 812.5 (the labeling of investigational devices) is included under § 812.20(b)(10), where the submitter is required to enclose a copy of the label that bears information required by § 812.5 (i.e., name and place of business of manufacturer, packer, or distributor, the quantity of contents if appropriate, and the following statement: ''CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use''). This label shall describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions. The label will also not bear any statement that is false or misleading in any particular and shall not represent that the device is safe or effective for the purposes for which it is being investigated. If the device is being used solely for animal research, the label shall bear the following statement: ''CAUTION-Device for investigational use in laboratory animals or other tests that do not involve human subjects.'' This section's burden is required under § 812.20(b)(10), therefore a separate burden estimate is not required.

This information will allow FDA to collect data to ensure that the use of the device will not present an unreasonable risk for the subject enrolled in the study and will not violate the subject's rights.

The likely respondents to this information collection will primarily be medical device manufacturers, investigators, hospitals, health maintenance organizations, and businesses.

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
812.10 (waiver requests)	0.0	0.0	0.0	0.50[1]	0.1[2]
812.20, 812.25, and 812.27 (original application)	500	0.428	214	80	17,120
812.35 and 812.150 (amendments and supplements)	500	6.86	3,430	6	20,580
Total					37,700

There are no capital costs or operating and maintenance costs associated with this collection of information.
[1]FDA's best estimate given the fact that no waiver request has ever been submitted.
[2]FDA's best estimate given the fact that no sponsor has submitted such a request between fiscal years 1991 and 1995.

Based on past conversations with manufacturers, industry and trade association representatives, and businesses, FDA has estimated that the annual reporting burden for one IDE original application takes approximately 80 hours to complete, and the annual reporting burden for one IDE amendment and supplement takes

approximately 6 hours to complete. The number of respondents who annually respond to this collection of information has decreased from 700 to 500, due to multiple applications received from each respondent.

Based on an average of IDE's submitted from fiscal years 1991 through 1995, approximately 500 respondents submit IDE applications (originals and supplements) annually. Based on data from fiscal years 1991 to 1995, an average of 214 original IDE applications are submitted annually.

The reporting burden for nonsignificant risk device studies is negligible. Normally, nonsignificant risk device studies are not reported to FDA unless a problem is reported such as an unanticipated adverse device reaction, failure to obtain informed consent, withdrawal of IRB approval, or a recall of a device. In the past, an average of 10 incidences or less annually have been reported to FDA.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
812.140 (original and supplement)	500	0.428	214	10	2,140
		6.86	3,430	1	3,430
812.140 (nonsignificant)	500	1	500	6	3,000
Total					8,570

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

Over the past several years, in conversations with manufacturers, industry trade association groups, and businesses, FDA has estimated that the recordkeeping burden for preparing an original IDE submission averages 10 hours for each original IDE submission. Similarly, through the same conversations mentioned above, FDA has estimated recordkeeping for each supplement requires 1 hour.

The recordkeeping burden for nonsignificant risk device investigations is difficult to estimate because nonsignificant risk device investigations are not required to be submitted to FDA. The IDE staff estimates that the number of nonsignificant risk device investigations is equal to the number of active significant risk device investigations. The recordkeeping burden, however, is reduced for nonsignificant risk device studies.

2. Information Required In A Premarket Notification Submission (21 CFR 807.87, 807.92, and 807.93) (OMB Control Number 0910–0281—Reinstatement)

Under section 510 of the act (21 U.S.C. 360), a premarket notification must be filed before the introduction or delivery for introduction of a device intended for human use. Under § 807.87 (21 CFR 807.87), premarket notifications are required to contain certain information, including the device name, establishment registration number, class of the device, the device's proposed labeling, action taken by the person required to register to comply with performance standards, and a 510(k) summary as described in 21 CFR 807.92 or a 510(k) (of the act) statement as described in § 807.93 (21 CFR 807.93). In addition, § 807.87(i) requires that those filing premarket notification who claim substantial equivalence to certain devices as described in § 807.87(i), that are classified into class III, must submit to FDA a summary of safety and effectiveness problems and a citation to the information upon which the summary is based. The premarket notification submitter must also furnish FDA with a certification that a reasonable search has been conducted of all known information.

The information collected in the premarket notification is necessary to enhance FDA's ability to ensure that only premarket notification submissions for devices that are as safe and as effective as legally marketed predicate devices are cleared for marketing. In addition, FDA makes publicly available this information concerning devices for which a marketing order has been issued, in order to provide to the public the agency's basis for equivalence determinations.

Respondents to this collection of information are medical device manufacturers and distributors.

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

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.87(h) and 807.92 (simple 510(k) summaries)	2,592	1	2,592	8	20,736
807.87(h) and 807.92 (complex 510(k) summaries)	247	1	247	12	2,964
807.87(h) and 807.93 (510(k) statements)	2,896	1	2,896	1	2,896
807.87(i) and 807.94 (certifications)	208	1	208	40	8,320
Total					34,916

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

FDA bases these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in the table above.

Under § 807.93, anyone submitting a 510(k) statement must make that information available to anyone who requests it.

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
807.93	2,896	10	28,960	0.5	14,480
Total					14,480

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

3. Administrative Detention and Banned Medical Devices (21 CFR 800.55, 800.55(k), 895.21, and 895.22) (OMB Control Number 0910–0114—Reinstatement)

FDA has the statutory authority under section 304(g) of the act (21 U.S.C. 334(g)), to detain during establishment inspections devices that are believed to be adulterated or misbranded. On March 9, 1979, FDA issued a final regulation on administrative detention procedures, which includes, among other things, certain reporting requirements (§ 800.55(g) (21 CFR 800.55(g))) and recordkeeping requirements (§ 800.55(k)). Under § 800.55(g), an applicant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, as well as records of distribution of the detained devices. These recordkeeping requirements for administrative detentions allow FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the act (21 U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. The final regulation for banned devices contains certain reporting requirements (§§ 895.21(d) and 895.22(a) (21 CFR 895.21(d) and 895.22(a))). Section 895.21(d) states that if the Commissioner of Food and Drugs (the Commissioner) decides to initiate a proceeding to make a device a banned device, a notice of proposed rulemaking will be published in the Federal Register, and this notice will contain the finding that the device presents a substantial deception or an unreasonable and substantial risk of illness or injury. The notice will also contain the reasons why the proceeding was initiated, an evaluation of data and information obtained under other provisions of the act, any consultations with the panel, and a determination as to whether the device could be corrected by labeling or change of labeling, or change of advertising, and if that labeling or change of advertising has been made. Under § 895.21(d), any interested person may request an informal hearing and submit written comments. Under § 895.22, a manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

Respondents to this collection of information are those manufacturers, distributors, or importers whose products FDA seeks to detain or ban. As previously stated, the collection of data and information under these regulations is conducted on a very infrequent basis and only as necessary.

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

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800.55(g)	1	1	1	25	25
895.21(d) and 895.22(a)[2]	0	0	0	0	0
Total					25

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

[2] No devices were banned during the past 3 years (§ § 895.21 and 895.22). Therefore, no burden has been imposed upon industry. When the prosthetic hair fibers were banned, there were no firms in the United States that were manufacturing or distributing the products. Thus, FDA has put zeroes in the columns estimating reporting and recordkeeping burdens.

TABLE 6.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
800.55(k)	1	1	1	20	20
Total					20

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

Over the past 3 years, there has been an average of one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained.

FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with one of the three firms whose devices had been detained over the last 3 years.

Dated: January 15, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–1481 Filed 1–21–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0003]

Dulal C. Chatterji; 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 Mr. Dulal C. Chatterji, 8025 Cobble Creek Circle, Potomac, MD 20854, 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 Mr. Chatterji was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Chatterji has notified FDA that he acquiesces to debarment and, therefore, has waived his opportunity for a hearing concerning this action.

EFFECTIVE DATE: November 1, 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: 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

Mr. Dulal C. Chatterji, formerly vice-president for scientific affairs and head of the research and development (R&D) division at Quad Pharmaceuticals, Inc. (Quad), pled guilty to, and on May 12, 1994, was sentenced for, obstructing an agency proceeding, a Federal felony under 18 U.S.C. 1505. The basis for this conviction was as follows:

In its new drug application (NDA) for colistimethate sodium, Quad falsely represented to FDA that it had produced three sterile batches of the drug. In fact, the firm had produced two nonsterile batches and only one sterile batch. During a subsequent FDA audit of Quad's R&D department, Mr. Chatterji directed that samples from the nonsterile batches of colistimethate sodium be destroyed.

Mr. Chatterji is subject to debarment based on a finding, under section 306(a) of the act (21 U.S.C. 355a(a)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Chatterji's conduct related to the regulation of a drug product because, in causing the destruction of drug samples, he obstructed FDA's investigation of fraudulent NDA data submitted by Quad.

In a letter received by FDA on November 1, 1995, Mr. Chatterji 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, Mr. Chatterji waived his opportunity for a hearing and any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.99), finds that Mr. Dulal C. Chatterji has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing findings and based on his notification of acquiescence, Mr. Dulal C. Chatterji 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 November 1, 1995, the date of notification of acquiescence (sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Chatterji, in any capacity, during his period of debarment, will be subject to civil money penalties. If Mr. Chatterji, 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 (ANDA's) submitted by or with the assistance of Mr. Chatterji during his period of debarment.

Any application by Mr. Chatterji for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 96N–0003 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: January 7, 1997.

Janet Woodcock

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–1477 Filed 1–21–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 91N–0404]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information regarding Medical Devices, Humanitarian Use Devices has been approved by the Office of Management and Budget (OMB), under the Paperwork Reduction Act of 1995. This document announces the OMB approval number.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–80), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 29, 1996 (61 FR 55804), the agency announced that the proposed information collection requirements on medical devices, humanitarian use devices (21 CFR 814.102, 814.104, 814.106. 814.108, 814.110(a), 814.112(b), 814.116(b), 814.118(d), 814.120(b), 814.124(b), 814.126(b)(i) and (ii)) had been submitted to OMB for review and clearance. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB has approved the collection of information and assigned OMB control number 0910–0332. The approval expires on November 30, 1999. Under 5 CFR 1320.5(b), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.