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 extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for filing objections and requests for a hearing on a regulation or order.

DATES: Submit written comments on the collection of information by December 27, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 extension 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 collection of information set forth 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.

Filing Objections and Requests for a Hearing on a Regulation or Order—21 CFR Part 12 (OMB Control Number 0910–0184—Extension)

Under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2)), within 30 days after publication of a regulation or order, any person adversely affected by such regulations or order may file objections and request a public hearing. The implementing regulations for these statutory requirements are found at 21 CFR 12.22, which sets forth the format and instructions for filing objections and requests for a hearing. Each objection for which a hearing has been requested must be separately numbered and specify with particularity the provision of the regulation or the proposed order objected to. In addition, each objection must include a detailed description and analysis of the factual information to be presented in support of the objection as well as any report or other document relied on, with some exceptions. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis only for the purpose of determining whether a hearing request is justified. The description and analysis do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

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
12.22	60	1	60	20	1,200

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

The burden estimate for this collection of information is based on agency data received on this administrative procedure for the past 3 years. Agency personnel responsible for processing the filing of objections and requests for a public hearing on a specific regulation or order, estimate approximately 60 requests are received by the agency annually, with each requiring approximately 20 hours of preparation time.

Dated: October 18, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–27698 Filed 10–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2097]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Humanitarian Use Devices

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.

DATES: Submit written comments on the collection of information by November 24, 1999.

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, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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

Medical Devices; Humanitarian Use Devices—21 CFR Part 814—Subpart H (OMB Control Number 0910–0332)—Extension

This collection implements the humanitarian use device (HUD) provision under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(m)) and part 814 (21 CFR part 814) subpart H. Under section 520(m) of the act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnosis a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted, and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnosis the disease or condition; and (3) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collection herein will allow FDA to determine whether to: (1) Grant HUD designation of a medical device, (2) exempt an HUD from the effectiveness requirements in sections 514 and 515 of the act provided that the device meets requirements set forth in section 520(m) of the act, and (3) grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making these determinations. Also, this information enables FDA to determine whether the holder of a humanitarian device exemption (HDE) is in compliance with the HDE requirements.

Description of Respondents: Businesses or others for-profit.

In the **Federal Register** of July 19, 1999 (64 FR 38673), the agency requested comments on the proposed collections of information. No significant comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.102	20	1	20	40	800
814.104(b) and (c)	15	1	15	320	4,800
814.106	15	4	60	50	3,000
814.108	12	1	12	80	960
814.116(d)(3)	1	1	1	1	1
814.124(a)	5	1	5	1	5
814.126(b)	1	1	1	2	2
814.126(b)(1)	15	1	15	120	1,800
Total					11,368

[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
814.126(b)(2)	15	1	15	2	30
Total					30

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

I. Explanation of Reporting Burden Estimate

Generally, the information requested from respondents represents an accounting of information already in the possession of the applicant.

In the **Federal Register** of June 26, 1996 (61 FR 33232), the agency issued a final rule for HUD's. FDA based its estimates on comments received on the proposed rule, industry contact, and internal FDA benchmark factors (such as the number of premarket approval applications processed). The numbers generated in the current estimate as shown in Tables 1 and 2 of this document and described in the following paragraphs, are based upon those prior estimates, and they have only been modified if actual numbers over the past 3 years have indicated a significantly different trend.

The first HUD rule became effective in fiscal year (FY) 1997, and FDA has only a few years of actual data to compare to original estimated numbers. Although actual numbers are less than the estimated numbers for this information collection, FDA believes that as manufacturers become more familiar with the program, FDA will experience

a larger number of submissions under the provisions discussed as follows:

Section 814.102 estimate assumes that 20 sponsors per year will submit a request for HUD designation. It is estimated to require 40 staff hours to complete each HUD designation request.

Section 814.104 estimate assumes that 15 sponsors per year will submit an HDE application after receiving HUD designation. FDA estimates that it will require an average of 320 staff hours to complete each HDE application.

Section 814.110(a) requires that a new indication for use of an HUD approved under this part be submitted as a new HDE application complying with § 814.104. All burden under this section is included under the estimate for § 814.104.

Section 814.106 estimate assumes that 4 times per year FDA will request or the sponsor will submit additional information or resubmit an HDE or HDE supplement for approximately 15 of the submitted HDE applications. FDA estimates that it will require the respondents to take an average of 50 staff hours to complete each amendment or resubmitted application. If FDA refuses to file the HDE application, requests for an informal conference (under § 814.112(b)) will be processed as an HDE amendment. Responses to approvable and not approvable letters (§ 814.116(b), (c), and (d)) will be processed as HDE amendments. A request for an opportunity for an informal hearing, prior to FDA issuing an order withdrawing approval, under § 814.118(d), will be processed as an HDE amendment. Because FDA only tracks amendments, and not the reasons for the amendment, the burden estimates for the sections listed in Tables 1 and 2 of this document are included in the burden estimate for § 814.106.

Section 814.108 estimate assumes that it will receive approximately 12 supplements for the submitted HDE applications. It is estimated that it will take approximately 80 staff hours to complete each supplemental application.

Section 814.116(d)(3) estimate assumes that it will receive approximately one request to withdraw an HDE application per year, based on withdrawals submitted in FY 1997 and FY 1998. FDA estimates it will take no longer than 1 staff hour to complete each written withdrawal notice.

Section 814.124(a) estimate assumes that five physicians will use HUD's in emergency situations before obtaining institute and review board (IRB) approval. FDA estimates that notification under this section will take an average of 1 hour per response.

Section 814.124(b) estimate assumes that one holder of an approved HDE will notify FDA of IRB withdrawal of approval. FDA estimates that it will take an average of 2 staff hours to notify FDA of IRB withdrawal.

Section 814.126(b)(1), following the implementation of the FDA Modernization Act, was amended to incorporate section 520(m)(5) of the act, which provides FDA the authority to require an HDE applicant to demonstrate continued compliance with the HDE requirements, if the agency believes that such a demonstration is necessary to protect the public health or has reason to believe that the criteria for the HDE exemption are no longer met. FDA amended this section to delete the requirement of an annual report and to include instead a periodic reporting requirement that will be established by the approval order for the HDE. This provision permits the agency to obtain sufficient information for it to determine whether there is reason to question the continued exemption of the device from the act's effectiveness requirements.

FDA anticipates that because of this amendment, the 15 HDE holders will remain active and therefore, estimates that 15 periodic reports will be received. FDA also estimates that it will take an average of 120 staff hours to complete a periodic report as a result of this amendment.

II. Explanation of Recordkeeping Burden Estimate

Section 814.126(b)(2) estimate assumes that 15 HDE holders per year will maintain records of certain required information. It is estimated that it will take an average of 2 staff hours to maintain this information.

Dated: October 18, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–27756 Filed 10–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4282]

Biotechnology in the Year 2000 and Beyond; Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing three public meetings on issues within FDA's jurisdiction related to foods (both human and animal) derived from plants developed using bioengineering techniques. The purpose of these public meetings is for the agency to share its current approach and experience over the past 5 years regarding safety evaluation and labeling of food products derived from bioengineered plant varieties, to solicit views on whether FDA's policies or procedures should be modified, and to gather information to be used to assess the most appropriate means of providing information to the public about bioengineered products in the food supply. These meetings will afford consumers, industry, and academia an opportunity to provide focused comment on these issues in a manner that will assist FDA in evaluating and refining its existing policies and procedures.

DATES: The meetings are scheduled as follows:

1. Thursday, November 18, 1999, 9 a.m. to 6 p.m., Chicago, IL.
2. Tuesday, November 30, 1999, 10 a.m. to 7 p.m., Washington, DC.
3. Monday, December 13, 1999, 9 a.m. to 6 p.m., Oakland, CA.

Submit written comments by January 13, 2000.

ADDRESSES: The meetings will be held at the following locations:

1. Chicago—One Prudential Plaza, Plaza Club, 40th floor,130 East Randolph St., Chicago, IL 60601.
2. Washington, DC— Grand Hyatt Washington, 1000 H St. NW., Washington, DC 20001.
3. Oakland—Elihu Harris State Office Building, 1515 Clay St., Oakland, CA 94612.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or via e-mail to www.fda.gov/ohrms/dockets. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For general information:

Nega Beru, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3090, FAX 202–418–3131, e-mail nberu@bangate.fda.gov.

For information about and registration for the public meeting in Chicago, IL:

Darlene Bailey, Chicago District (HFR–CE 645), Food and Drug Administration, 300 S. Riverside