**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:** Peggy R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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 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.

**Citizen Petition—21 CFR 10.30 (OMB Control Number 0910–0183—Reinstatement)**

The Administrative Procedures Act (5 U.S.C. 553(e)), provides that every agency shall accord any interested person the right to petition for issuance, amendment, or repeal of a rule. Section 10.30 (21 CFR 10.30) provides that any person may submit to the agency a citizen petition requesting the Commissioner of Food and Drugs to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

The information is used by the agency to determine the need or desirability of the requested action and also to determine if the submitted information is sufficient to support the action. FDA determines whether or not to grant the petition based on the information submitted.

The affected respondents are individuals or households, state or local governments, not-for-profit institutions and businesses or other for-profit institutions or groups.

FDA estimates the burden resulting from the requirements of § 10.30 as follows:

ESTIMATED ANNUAL REPORTING BURDEN

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 10.30 | 120 | 1 | 120 | 12 | 1,440 |

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

The agency bases this estimate of burden on fiscal year 1995 data in which there were 120 petitions filed that each took an estimated 12 hours to complete.

Dated: November 27, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96–31052 Filed 12–5–96; 8:45 am]

**BILLING CODE 4160–01–F**

**[Docket No. 96N–0426]**

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

**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, 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 February 4, 1997.

**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, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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 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.

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 the collection of information provisions for these regulations as follows:

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 |

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: November 27, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96–31054 Filed 12–5–96; 8:45 am]

**BILLING CODE 4160–01–F**

**[Docket No. 96N–0261]**

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

**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 January 6, 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, Attn: Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Judy 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 Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reclassification Petitions for Medical Devices—21 CFR Part 860—(OMB Control Number 0910–0138—Reinstatement)

Under sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e) and (f), 360d(b), 360e(b), and 360j(l)) and 21 CFR part 860, subpart C, FDA has the responsibility to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a medical device from any one of three classes (I, II, and III) to another class. The reclassification procedures regulation (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed classification will provide a reasonable assurance of safety and effectiveness of the device for its intended use. The reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device. The reclassification petitions requesting classification from class III to class II or class I, if approved, provide an alternative route to the market in lieu of premarket approval for class III devices.

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