

FOR FURTHER INFORMATION CONTACT:

Sandra M. Peay or Parcellena P. Fielding, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, DC 20580, (202) 326-3100.

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1072]

Agency Information Collection Activities: Proposed Collection; Comment Request; Administrative Detention and Banned Medical Devices

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 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 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 collection of information by May 30, 2000.

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: Peggy Schlosburg, Office of Information

Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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 in this document.

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.

Administrative Detention and Banned Medical Devices—21 CFR 800.55(g), 800.55(k), 895.21, and 895.22 (OMB No. 0910-0114)—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (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.

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 |
|---------------------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 800.55(g) | 1 | 1 | 1 | 25 | 25 |
| 895.21(d) and 895.22(a) and (c) | 26 | 1 | 26 | 16 | 416 |
| TOTALS | | | | | 441 |

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 |
|----------------|----------------------|------------------------------------|----------------------|------------------------|-------------|
| 800.55(k) | 1 | 1 | 1 | 20 | 20 |

¹ 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. Historically, FDA's Center for Devices and Radiological Health (CDRH) has had very few or no annual responses for this information collection and normally reports one response per year. CDRH is anticipating a banning action in Fiscal Year 2000 that will involve 26 firms.

Dated: March 24, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-7932 Filed 3-30-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1061]

Agency Information Collection Activities: Proposed Collection; Comment Request; Resource Assessment of Programs and Services in Food Safety

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 notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the

notice. This notice solicits comments on a project supported by FDA to collect information on food safety programs and services and the resources devoted thereto by State and local agencies nationwide.

DATES: Submit written comments on the collection of information by May 30, 2000.

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. Capezuto, 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, 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 in this document.

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.

Assessment of Local and State Resources in Food Safety Programs and Services

In 1998, FDA began an effort, in cooperation with local, State, and other Federal agencies, to develop an integrated national food safety system. The system would coordinate the activities and resources of all levels of government devoted to regulatory food safety programs to maximize the impact of available resources, reduce overlapping functions, coordinate responses to foodborne disease outbreaks, share information, improve communications and training, establish minimum national uniform standards and identify gaps in food safety controls for correction at any level of government. The effort is consistent with the "farm to table" approach and sound scientific and risk-based priorities called for by the National Academy of Science's Report of August 20, 1998, and the President's Council on Food Safety, established by Executive Order 13100 on August 25, 1998. A number of workgroups of local, State,