Dated: December 1, 2005.

Joan Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E5–7040 Filed 12–7–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0186]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''State Enforcement Notifications'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 14, 2005 (70 FR 54393), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0275. The approval expires on November 30, 2008. A copy of the supporting statement for this information collection is available on the Internet at ''*http://www.fda.gov/ohrms/dockets*''.

Dated: November 30, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23744 Filed 12–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0457]

Agency Information Collection Activities; Proposed Collection; Comment Request; Notice of a Claim for Generally Recognized as Safe Exemption Based on a Generally Recognized as Safe Determination

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 the procedures used for submitting a Generally Recognized as Safe (GRAS) notice stating that a particular use of a substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Submit written or electronic comments on the collection of information by February 6, 2006.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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 Robbins, Office of Management Programs (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 these topics: (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.

Notice of a Claim for GRAS Exemption Based on a GRAS Determination—21 CFR 170.36 and 570.36 (OMB Control Number 0910–0342)—Extension

Section 409 of the act (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives;'' section 201(s) of the act (21 U.S.C. 321(s)) provides an exemption from the definition of ''food additive'' and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. FDA is proposing a voluntary procedure whereby members of the food industry who determine that use of a substance satisfies the statutory exemption may notify FDA of that determination. The notice would include a detailed summary of the data and information that support the GRAS determination, and the notifier would maintain a record of such data and information. FDA would make the information describing the GRAS claim, and the agency's response to the notice, available in a publicly accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act and other Federal disclosure statutes.

Description of Respondents: Manufacturers of Substances Used in Food and Feed.

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
170.36	50	1	50	150	7,500
570.36	10	1	10	150	1,500
Total					9,000

[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 Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
170.36(c)(v)	50	1	50	15	750
570.36(c)(v)	10	1	10	15	150
Total					900

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

The reporting requirement is for a proposed rule that has not yet been issued as a final rule. In developing the proposed rule, FDA solicited input from representatives of the food industry on the reporting requirements, but could not fully discuss with those representatives the details of the proposed notification procedure. FDA received no comments on the agency's estimate of the hourly reporting requirements, and thus has no basis to revise that estimate at this time. In 1998, FDA began receiving notices that were submitted under the terms of the proposed rule. Since it began receiving notices, FDA has received 12 in 1998, 23 in 1999, 30 in 2000, 28 in 2001, 26 in 2002, 23 in 2003, 20 in 2004, and 22 to date in 2005, notices annually. To date, the number of annual notices is less than FDA's estimate; however, the number of annual notices could increase when the proposed rule becomes final. FDA received 23 notices in 1999, 30 notices in 2000, 28 notices in 2001, 26 notices in 2002, 23 notices in 2003, and 20 notices in 2004.

Dated: November 30, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23747 Filed 12–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0434]

Draft Guidance for Industry and Food and Drug Administration; Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens.'' This draft guidance document is being issued to provide guidance on the types of information and data to consider when preparing or reviewing premarket submissions for nucleic acid based in vitro diagnostic devices for the detection of microbial pathogens.

DATES: Submit written or electronic comments on this draft guidance by March 8, 2006.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or FAX your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Roxanne Shively, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0496 ext. 113.

SUPPLEMENTARY INFORMATION:

I. Background

This draft document is intended to provide a basic framework for the types of information and data that we believe should be addressed in the premarket review of a nucleic acid based device for detecting microbial pathogens. This draft guidance replaces a previously issued document entitled ''Review Criteria for Nucleic Acid Amplification-based in vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms'' (June 1993). The current draft reflects changes in the technologies available for nucleic acid detection, and expanded use in clinical laboratories. The recommendations within this draft guidance apply broadly to premarket review of these in vitro diagnostic devices for detecting microbial pathogens. Enzymatic amplification may or may not be part of the applied technology.