DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0433]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter

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 extending the Office of Management and Budget (OMB) approval on the existing reporting requirements for the information collection activity entitled ''How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter.''

DATES: Submit written or electronic comments on the collection of information by January 8, 2007.

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: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from 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.

Guidance for Industry on How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter—21 CFR 514.117(b)(2) and 21 CFR 511.1(b)(5); (OMB Control Number 0910–0453)—Extension

The Center for Veterinary Medicine (CVM) monitors the final disposition of investigational animals where such animals do not enter the human food chain immediately at the completion of the investigational study. CVM's monitoring of the final disposition of investigational food animals is intended to ensure that unsafe residues of new animal drugs do not get into the food supply. CVM issues a slaughter authorization letter to investigational new animal drug (INAD) sponsors that sets the terms under which investigational animals may be slaughtered (21 CFR 511.1(b)(5)). Also in this letter, CVM requests that sponsors submit a notice of final disposition of investigational animals (NFDA) not intended for immediate slaughter. NFDAs have historically been submitted to CVM on paper. CVM's guidance ''How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter'' provides sponsors with the option to submit an NFDA as an e-mail attachment to CVM via the Internet.

The likely respondents are INAD sponsors.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/ Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses[2]	Hours per Response	Total Hours
511.1(b)(5)/Form FDA 3487	25	1.44	36	.08	2.88

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Electronic submissions received between July 1, 2005, and June 30, 2006.

The number of respondents in table 1 are the number of sponsors registered to make electronic submissions (25). The number of total annual responses is based on a review of the actual number of such submissions made between July 1, 2005, and June 30, 2006 (36 x hours per response (.08) = 2.88 total hours).

Dated: November 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0183]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 11, 2006.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Guidance on Reagents for Detection of Specific Novel Influenza A Viruses—21 CFR 866.3332 (OMB Control Number 0910–0584)—Extension

In accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA evaluated an application for an in vitro diagnostic device for detection of influenza subtype H5 (Asian lineage), commonly known as avian flu. FDA concluded that this device is properly classified into class II in accordance with section 513(a)(1)(B) of the act, because it is a device for which the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance. The statute permits FDA to establish as special controls many different things, including postmarket surveillance, development and dissemination of guidance, recommendations, and ''other appropriate actions as the Secretary deems necessary'' (section 513(a)(1)(B) of the act). This information collection is a measure that FDA determined to be necessary to provide reasonable assurance of safety and effectiveness of reagents for detection of specific novel influenza A viruses.

FDA issued an order classifying the H5 (Asian lineage) diagnostic device into class II on February 3, 2006, establishing the special controls necessary to provide reasonable assurance of the safety and effectiveness of that device and similar future devices. The new classification will be codified in 21 CFR 866.3332, a regulation that will describe the new classification for reagents for detection of specific novel influenza A viruses and set forth the special controls that help to provide a reasonable assurance of the safety and effectiveness of devices classified under that regulation. The regulation will refer to the special control guidance document, ''Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses,'' which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for these reagents.

The guidance document recommends that sponsors obtain and analyze postmarket data to ensure the continued reliability of their device in detecting the specific novel influenza A virus that it is intended to detect, particularly given the propensity for influenza viruses to mutate and the potential for changes in disease prevalence over time. As updated sequences for novel influenza A viruses become available (from the World Health Organization, National Institutes for Health, and other public health entities), sponsors of reagents for detection of specific novel influenza A viruses will collect this information, compare them with the primer/probe sequences in their devices and incorporate the result of these analyses into their quality management system, as required by 21 CFR 820.100(a)(1). These analyses will be evaluated against the device design validation and risk analysis required by 21 CFR 820.30(g), to determine if any design changes may be necessary.

FDA considered comments expressed by the Centers for Disease Control and Prevention before the issuance of this guidance.

FDA also published a notice in the **Federal Register** of May 22, 2006 (71 FR 29342) soliciting comments on this information collection as required under 5 CFR 1320.8(d). In response, FDA received one comment concerning this information collection. The comment pointed out that the estimated hours per response should be closer to 15, rather than FDA's estimate of 10 hours, in order to comply with quality system regulation/document control for the new information collection. FDA agrees with this comment and as a result, the annual reporting burden hour estimate has been recalculated accordingly, i.e., the total annual reporting burden hour estimate is now 300 hours instead of 200.

Respondents to this collection of information are manufacturers of in vitro diagnostic devices.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating and Maintenance Costs
10	2	20	15	300	$3,500