caused or contributed to death or serious injury or has malfunctioned in such a way that should the malfunction recur, it would be likely to cause or contribute to a death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown, then the reports are sent to FDA.

The number of respondents for each CFR section in table 1 of this document is based upon the number of respondents entered into FDA's internal databases. FDA estimates, based on its experience and interaction with the medical device community, that all reporting CFR sections are expected to take 1 hour to complete, with the exception of § 803.19. Section 803.19 is expected to take approximately 3 hours to complete, but is only required for reporting the summarized data quarterly to FDA. By summarizing events, the total time used to report for this section is reduced because the respondents do not submit a full report for each event they report in a quarterly summary report.

The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the medical device reporting (MDR) requirements as part of their internal quality control system. There are an estimated 30,000 medical device distributors. Although they do not submit MDR reports, they must maintain records of complaints, under § 803.18(d).

The agency has estimated that on average, 220 user facilities, importers, and manufacturers would annually be required to establish new procedures, or revise existing procedures, in order to comply with this provision.

Therefore, FDA estimates the one-time burden to respondents for establishing or revising procedures to be 2,200 hours (220 respondents x 10 hours). For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers, not required to revise their written procedures to comply with this provision, are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered ''usual and customary'' under 5 CFR 1320.3(b)(2).

The annual burden for recordkeeping to respondents follows. Under § 803.17, FDA estimates 220 respondents will spend approximately 3.3 hours to complete the requirements for this section. The number of respondents was estimated by consolidating the total of all new reporting entities together. The 3.3 hours was estimated by FDA, as this section deals with a respondent creating new MDR procedures and is a one-time function. The ''total hours'' for this section equals approximately 726 hours.

Under § 803.18, 30,000 respondents represent distributors, importers, and other respondents to this information collection. FDA estimates that it should take them approximately 1 1/2 hours to complete the recordkeeping requirement for this section. Total hours for this section equal 45,000 hours.

Dated: March 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–4426 Filed 3–27–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0118]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for 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 collection of information entitled ''Guidance for Reagents for Detection of Specific Novel Influenza A Viruses'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: 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 0910–0584. The approval expires on September 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: March 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0508]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of Health Care Practitioners Regarding Their Preferences for Public Health Notifications

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 April 27, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (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.

Survey of Health Care Practitioners Regarding Their Preferences for Public Health Notifications (PHNs)

The PHN is one of the tools that the Center for Devices and Radiological Health (CDRH) uses to get an important message to the user community about risks associated with the use of medical devices. This particular tool is meant to serve a specific purpose not served by the other communication tools at our