DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0231]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Adverse Experience Reporting for Licensed Biological Products; and General Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Adverse Experience Reporting for Licensed Biological Products; and General Records'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–7726, *ila.mizrachi@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On July 19, 2011, the Agency submitted a proposed collection of information entitled ''Adverse Experience Reporting for Licensed Biological Products; and General Records'' 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 0910–0308. The approval expires on November 30, 2014. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: November 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30326 Filed 11–23–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0350]

Agency Information Collection Activities; Proposed Collection; Comment Request; Draft Guidance for Tobacco Retailers on Tobacco Retailer Training Programs

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 the information collection provisions of the draft guidance entitled ''Tobacco Retailer Training Programs.''

DATES: Submit written or electronic comments on the collection of information by January 24, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–5156, *daniel.gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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, in the **Federal Register** of July 16, 2010 (75 FR 41498), FDA published a notice of availability of the draft guidance document providing a 60-day public comment period on the collection of information provisions. An electronic version of the guidance document is available on the Internet at http://www.regulations.gov (Docket No. FDA–2010–D–0350) and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*. FDA received seven comments in response to the notice of availability, with four comments pertaining to the information collection.

FDA is republishing notice of the proposed collection of information in order to comply with section 3506(c)(2)(A) of the PRA. We invite comments only on the proposed collection of information set forth in this document. FDA will respond to comments on the collection of information provisions received in response to this notice and to the July 16, 2010, notice in a 30-day notice announcing that a proposed collection of information has been submitted to OMB for review and clearance under the PRA.

With respect to the collection of information associated with the draft guidance, 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.

Information Request Regarding Draft Guidance for Tobacco Retailers on Tobacco Retailer Training Programs (OMB Control Number 0910–New)

The Tobacco Control Act does not require retailers to implement retailer training programs. However, the statute does provide for lesser civil money penalties for violations of access, advertising, and promotion restrictions of regulations promulgated under section 906(d) of the Federal Food,