which workers, in the event of respiratory protection failure (*e.g.,* contaminant breakthrough in a cartridge respirator or stoppage of air flow in a supplied-air respirator), could escape safely when the exposure was below the IDLH value.

Since the establishment of the original IDLH values in 1974, NIOSH has continued to review the available scientific data to improve the protocol used to derive the acute exposure guidelines, in addition to the chemical-specific IDLH values. This draft CIB represents the most recent update of the scientific rationale and process used to derive IDLH values based on health effects considerations determined through a critical assessment of the toxicology and human health effects data.

The new process relies on a weight-of-evidence approach based on scientific judgment for establishing IDLH values that allows for the critical evaluation of the quality and consistency of the scientific data, and in extrapolation from the available data to the IDLH value. The weight-of-evidence approach refers to the critical examination of all the available data from diverse lines of evidence and the derivation of a scientific interpretation based on the collective body of data including its relevance, quality and reported results. Guidelines are presented to aid in the selection of the critical adverse effect, a point of departure (POD) or the point on the dose-response curve from which dose extrapolation is initiated, and applying default uncertainty factors (UFs) to derive the IDLH value. Conceptually, the derivation process presented in this CIB is similar to that used in other risk assessment applications including the process steps of:

- Hazard characterization,
- Identification of critical adverse effects,
- Identification of a POD,
- Application of an appropriate UF based on the study and POD, and
- Determination of the final risk value.

Supplemental information included within this draft CIB includes (1) An overview of the literature search strategy used to identify relevant data, (2) the scheme used to prioritize and select chemicals for which an IDLH value will be established and (3) an overview of the analysis applied by NIOSH to develop a scientifically-based approach for the selection of the UF during the derivation of IDLH values. In addition, Appendix A of the draft CIB presents an example of the derivation of an IDLH value for vinyl acetate (CAS #108–50–4) based on the new process.

Dated: January 13, 2011.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2011–1301 Filed 1–21–11; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0044]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products

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 information request regarding the Guidance for Industry and FDA Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products.

DATES: Submit either electronic or written comments on the collection of information by March 25, 2011.

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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr. PI50–400B, Rockville, MD 20850. 301–796–3794. *Jonnalynn.Capezzuto@fda.hhs.gov*.

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.

Information Request Regarding Guidance for Industry and FDA Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products (OMB Control Number 0910–0673—Extension)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 905(j) of the FD&C Act authorizes FDA to establish the form for the submission of information related to

substantial equivalence (21 U.S.C. 387e(j)). In a level 1 guidance document issued under the Good Guidances Practices regulation (21 CFR 10.115), FDA provides recommendations intended to assist persons submitting reports under section 905(j) of the FD&C Act, and explains, among other things, FDA's interpretation of the statutory sections related to substantial equivalence.

Estimation of Burden

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FD&C Act sections	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
905(j) and 910(a)	150	1	150	360	54,000
Total					54,000

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

FDA has based these estimates on information related to other regulated products and FDA's expectations regarding the tobacco industry's use of the 905(j) pathway to market their products. Table 1 of this document describes the annual reporting burden as a result of the implementation of the substantial equivalence requirements of sections 905(j) and 910(a) of the FD&C Act (21 U.S.C. 387e(j) and 387j(a)). FDA estimates that it will receive 150 section 905(j) reports each year and that it will take a manufacturer approximately 360 hours to prepare a report of substantial equivalence for a new tobacco product. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 54,000 hours.

Dated: January 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1276 Filed 1–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0110]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Advertisements

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 February 23, 2011.

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: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–new and title "Prescription Drug Advertisements". Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850. 301–796–3792. *Elizabeth.Berbakos@fda.hhs.gov*.

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.

Prescription Drug Advertisements—(OMB Control Number 0910)—New

Section 502(n) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352(n)) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs and biologics, section 502(n) of the FD&C Act requires advertisements to contain "* * * a true statement * * *" of certain information including "* * * information in brief summary relating to side effects, contraindications, and effectiveness * * *" as required by regulations issued by FDA. FDA's prescription drug advertising regulations at § 202.1 (21 CFR 202.1) describe requirements and standards for print and broadcast advertisements. Section 202.1 applies to advertisements published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems. Print advertisements must include a brief summary of each of the risk concepts from the product's approved package labeling (§ 202.1(e)(1)). Advertisements that are broadcast through media such as television, radio, or telephone communications systems must disclose the major risks from the product's package labeling in either the audio or audio and visual parts of the presentation (§ 202.1(e)(1)); this disclosure is known as the "major statement." If a broadcast advertisement omits the major statement, or if the major statement minimizes the risks associated with the use of the drug, the advertisement could render the drug misbranded in violation of the FD&C Act, (21 U.S.C. 352(n) and section 201 of the FD&C Act (21 U.S.C. 321(n)), and FDA's implementing regulations at § 202.1(e).

Advertisements subject to the requirements at § 202.1 are subject to the PRA because these advertisements disclose information to the public. In addition, § 202.1(e)(6) and (j) include provisions that are subject to OMB approval under the PRA. The information collection requirements in § 202.1 have not previously been submitted to OMB for approval. With this notice, we are seeking comment on the proposed information collection.

Reporting to FDA

Section 202.1(e)(6) includes a provision that is subject to the PRA. Section 202.1(e)(6) permits a person who would be adversely affected by the enforcement of a provision of