Dated: February 28, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–5356 Filed 3–6–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0452]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by April 7, 2003.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW. rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

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

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.

New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

FDA has amended its new drug and biological product regulations to allow appropriate studies in animals in certain cases to provide substantial evidence of effectiveness of new drug and biological products used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances when adequate and well-controlled efficacy studies in humans cannot be ethically conducted because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers and field trials are not feasible prior to approval. In these circumstances, when it may be impossible to demonstrate effectiveness through adequate and well-controlled studies in humans, FDA is providing that certain new drug and biological products intended to treat or prevent serious or life-threatening conditions could be approved for marketing based on studies in animals, without the traditional efficacy studies in humans. FDA is taking this action because it recognizes the importance of improving medical responses capabilities to the use of lethal or permanently disabling chemical, biological, radiological, and nuclear substances in order to protect individuals exposed to these substances.

Respondents to this information collection are business and other for-profit organizations, and nonprofit institutions.

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
314.610(b)(2), 314.630, 601.91(b)(2), and 601.93	1	1	1	5	5
314.610(b), 314.640, 601.91(b), and 601.94	1	1	1	240	240
Total					245

[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 Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
314.610(b)(2), 314.630, 601.91(b)(2), and 601.93	1	1	1	1	1
314.610(b), and 601.91(b)	1	1	1	1	1
Total					2

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

FDA estimates that only one application of this nature may be submitted every 3 years, however, for calculation purposes. FDA is estimating the submission of one application annually. FDA estimates 240 hours for a manufacturer of a new drugs or biological product to develop patient labeling and to submit the appropriate information and promotional labeling to FDA. At this time, FDA cannot estimate the number of postmarketing reports for information collection. These reports are required under 21 CFR parts 310, 314, and 600. Any requirements will be reported under the adverse experience reporting (AER) information collection requirements. The estimated hours for postmarketing reports range from 1 to 5 hours based on previous estimates for AER; however, FDA is estimating 5

hours for the purpose of this information collection.

The majority of the burden for developing the patient labeling is included under the reporting requirements; therefore, minimal burden is calculated for providing the guide to patients. As discussed previously, no burden can be calculated at this time for the number of AER reports that may be submitted after approval of a new drug or biologic. Therefore, the number of records that may be maintained also cannot be determined. Any burdens associated with these requirements will be reported under the AER information collection requirements. The estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER system.

FDA, in the **Federal Register** of November 13, 2002 (67 FR 68874), the agency requested comments on the proposed collection of information. No comments were received.

Dated: February 28, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0528]

Risk Management; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop, request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to discuss risk management activities for drug and biological products (excluding blood products other than plasma derivatives). The purpose of the workshop is to present FDA's current thoughts on risk management activities and to solicit views from the public. To facilitate public input and discussion, FDA is issuing for review and comment three concept papers that focus on risk assessment, risk management, and pharmacovigilance. The input received at the workshop and from comments on the concept papers will be considered in drafting guidance for industry.

DATES: The public workshop will be held on April 9, 10, and 11, 2003, from 8 a.m. to 4:30 p.m. Submit written or electronic requests to preregister to speak by March 21, 2003. Written or electronic comments on the concept papers will be accepted until April 30, 2003. However, to have your comments considered at the workshop, submit them by March 21, 2003.

ADDRESSES: The public workshop will be held at the National Transportation Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594; 202–314–6421. The center may be reached by Metro, using the L'Enfant Plaza Station on the green, yellow, blue, and orange lines) http://www.ntsb.gov/events/newlocation.htm. Seating is limited and will be available on a first-come first-served basis each day of the workshop.

Submit written or electronic requests to speak and comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852; e-mail FDADockets@oc.fda.gov; or on the Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Transcripts of the workshop will be available for review at the Dockets Management Branch (see address above) and on the Internet at http://www.fda.gov/ohrms/dockets.

FOR FURTHER INFORMATION CONTACT:

For media and press inquiries: Jason Brodsky, Office of Public Affairs (HFI–020), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301–827–6242, jbrodsky@oc.fda.gov.

For all other inquiries: Lee Lemley, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6218, lemleyl@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188), which includes the Prescription Drug User Fee Amendments of 2002 (Public Law 102–571) (PDUFA 3). In exchange for receiving user fees under PDUFA 3, FDA agreed to certain performance goals. As one of its PDUFA 3 goals, FDA agreed to produce guidance for industry on risk management activities. Specifically, FDA intends to produce three guidance documents by September 30, 2004, addressing: Good risk assessment, risk management, and pharmacovigilance practices for drug and biological products (excluding blood products other than plasma derivatives). As an initial step, three joint Center for Drug Evaluation and Research (CDER)/Center for Biologics Evaluation and Research (CBER) working groups have developed concept papers outlining FDA's preliminary thoughts for providing guidance for industry. The concept papers are available at FDA's Dockets Management Branch and on the Internet (http://www.fda.gov/cder/meeting/riskmanagement.htm). FDA welcomes written and electronic comments on the concept papers (see section IV of this document).

II. Scope of Workshop and Concept Papers

At this public workshop, FDA is interested in receiving comments from stakeholder groups likely to be affected by its risk management activities. Stakeholder groups of interest include, but are not limited to: Consumer groups, physicians, nurses, pharmacists, drug and biological product manufacturers, and third party payers for health care services and medical products.

Each day of the 3-day workshop will focus on one aspect of risk management activities, including: (1) Premarketing risk assessment on April 9, 2003, (2) risk management programs and planning on April 10, 2003, and (3) pharmacovigilance and pharmacoepidemiologic assessment on April 11, 2003.

A. Premarketing Risk Assessment (April 9, 2003)

Risk assessment is the process of identifying, estimating, and evaluating the nature and severity of risks associated with a product throughout its lifecycle. On April 9, 2003, the public workshop discussion will focus on good risk assessment practices during product development. Specifically, the discussion will focus on issues raised by the concept paper ''Premarketing Risk Assessment'' (http://www.fda.gov/cder/meeting/riskmanagement.htm). This concept paper presents FDA's preliminary thoughts on:

1. Important risk assessment concepts,
2. Generation and acquisition of safety data during clinical trials, and
3. Analysis and presentation of safety data in an application for approval

B. Risk Management Programs and Planning (April 10, 2003)

Risk management is the overall and continuing process of minimizing risks throughout a product's lifecycle to optimize its benefit/risk balance. On April 10, 2003, the public workshop discussion will focus on the