Application No.	Drug	Applicant
ANDA 84–446	Phenaphen with Codeine (acetaminophen and codeine phosphate capsules USP) No. 4 Capsules	Do.
ANDA 85–328	Theo-Dur (theophylline) Extended-Release Tablets, 100 mg and 300 mg	Schering Corp.
ANDA 85–632	Quinidine Sulfate Tablets USP, 300 mg	Roxane Laboratories, Inc.
ANDA 86–134	Nitro-Bid Ointment (nitroglycerin ointment USP, 2%)	Altana Inc., 60 Baylis Rd., Melville, NY 11747
ANDA 86–348	Prochlorperazine Edisylate Injection USP, 5 mg (base)/mL	Wyeth Pharmaceuticals
ANDA 86–998	Theo-Dur (theophylline) Extended-Release Tablets, 200 mg	Schering Corp.
ANDA 88–584	DHCplus (dihydrocodeine bitartrate, acetaminophen, and caffeine) Capsules, 356.4 mg	Purdue Frederick Co., One Stamford Forum, Stamford, CT 06901–3431
ANDA 89–116	Brompheril (dexbrompheniramine maleate/pseudoephedrine sulfate) Extended-Release Tablets, 6 mg/120 mg	Copley Pharmaceuticals, Inc., c/o Teva Pharmaceuticals, 1090 Horsham Rd., North Wales, PA 19454
ANDA 89–131	Theo-Dur (theophylline) Extended-Release Tablets, 450 mg	Schering Corp.
ANDA 89–386	Cycrin (medroxyprogesterone acetate) Tablets, 10 mg	Wyeth Pharmaceuticals
ANDA 89–573	Methylprednisolone Sodium Succinate for Injection USP, 40 mg	Abbott Laboratories
ANDA 89–574	Methylprednisolone Sodium Succinate for Injection USP, 125 mg	Do.
ANDA 89–575	Methylprednisolone Sodium Succinate for Injection USP, 500 mg	Do.
ANDA 89–576	Methylprednisolone Sodium Succinate for Injection USP, 1000 mg	Do.
ANDA 89–822	Uni-Dur (theophylline) Extended-Release Tablets, 400 mg	Schering Corp.
ANDA 89–823	Uni-Dur (theophylline) Extended-Release Tablets, 600 mg	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research by the Commissioner, approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective June 4, 2004.

Dated: March 22, 2004.

Steven K. Galson,

Acting Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 04–10194 Filed 5–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004D–0187, 2004D–0188, and 2004D–0189]

Draft Guidances for Industry on Premarketing Risk Assessment; Development and Use of Risk Minimization Action Plans; and Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three draft guidances for industry entitled ''Premarketing Risk Assessment,'' ''Development and Use of Risk Minimization Action Plans,'' and ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' All are dated May 2004. These draft guidances provide guidance to industry on risk management activities for drug products, including biological drug products, in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The draft guidances address, respectively, premarket risk assessment; the development, implementation, and evaluation of risk minimization action plans for drug products; and good pharmacovigilance practices and pharmacoepidemiologic assessment of observational data.

DATES: Submit written or electronic comments on the draft guidances by July 6, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify each set of comments with the corresponding docket number of the draft guidance as follows: Docket No. [2004D–0187] ''Premarketing Risk Assessment,'' Docket No. [2004D–0188] ''Development and Use of Risk Minimization Action Plans,'' and Docket No. [2004D–0189] ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance documents.

FOR FURTHER INFORMATION CONTACT: For ''Premarketing Risk Assessment'': Barbara Gould, Center for Drug Evaluation and Research (HFD–550), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2504, or

Patricia Rohan, Center for Biologics Evaluation and Research (HFM–485), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3070.

For ''Development and Use of Risk Minimization Action Plans'': Christine Bechtel, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–443–5572, or

Mark Weinstein, Center for Biologics Evaluation and Research (HFM–300), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3518.

For ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment'': Patrick Guinn, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–443–5590, or

Miles Braun, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of three draft guidances for industry entitled ''Premarketing Risk Assessment,'' ''Development and Use of Risk Minimization Action Plans,'' and ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' These three guidances were produced in part to fulfill FDA's commitment to certain risk management performance goals agreed to in relation to the Prescription Drug User Fee Act upon its reauthorization in June 2002. As an initial step, FDA announced on March 7, 2003 (68 FR 11120), the availability of three concept papers. Each concept paper focused on one aspect of risk management. FDA held a public workshop on April 9–11, 2003, to obtain comment on the concept papers. The comments submitted on the concept papers and at the public meeting were considered in developing these draft guidances.

These three draft guidances address risk management issues pertinent to the successive stages of a product's lifecycle, specifically: (1) During medical product development, (2) during product application review and approval, and (3) during the postmarketing period. The approaches recommended in the draft guidances should not be viewed as a new collection of generalized and discrete tools for risk minimization but rather as part of much broader, ongoing, and comprehensive efforts to provide additional guidance to industry on measures that can be employed to minimize the risks while preserving benefits of medical products.

The draft guidances recommend that sponsors consider specific risk minimization efforts beyond routine risk minimization measures for the few products presenting unusual types or levels of risk. In these circumstances, using strategies that go beyond routine risk assessment and minimization may further improve the product's benefit-risk balance. FDA is specifically soliciting public comment on how to best characterize the types and levels of risk that might suggest the need for a risk management plan.

FDA understands that risk management programs generate costs and place new burdens on product developers, health care practitioners, and patients. FDA recommends that, whenever possible, sponsors give every consideration to using the least burdensome method to achieve the desired public health outcome. For example, making increasing use of automatic reporting and future notification systems for adverse events will help the agency learn quickly of potential problems. Use of networks for electronic prescribing can enable the real-time, efficient collection of data on adverse events and even alert physicians to adverse events at the time of prescribing.

As new products are developed, FDA recommends that sponsors seek to identify risk signals as early as possible in a product's development cycle, to evaluate the risks, to communicate predictable risk and benefit information effectively and thoroughly, and to employ efforts to manage these risks as efficiently as possible.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidances, when finalized, will represent the agency's current thinking on these topics. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidances. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document. Identify each set of comments with the corresponding docket number of the draft guidance as follows: Docket No. [2004D–0187] ''Premarketing Risk Assessment,'' Docket No. [2004D–0188] ''Development and Use of Risk Minimization Action Plans,'' and Docket No. [2004D–0189] ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' The draft guidances and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

These guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection(s) of information in the guidances were approved under OMB control numbers 0910–0001 (until

March 31, 2005) and 0910–0338 (until August 31, 2005).

IV. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 26, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–10028 Filed 5–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Graduate Student Training Programs Application

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Graduate Partnerships Program/OIR/OD, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Graduate Student Training Programs Application. *Type of Information Collection Request:* Extension. *Form Number:* 0925–0501. *Expiration Date:* June 30, 2005. *Need and Use of Information Collection:* The information gathered in the Graduate Student Training Programs application will enable the identification and evaluation of graduate students interested in performing their dissertation research in the NIH Intramural Research Program laboratories (NIH–IRP). Modeling university applications for admission into graduate programs, the Graduate Student Training Program application contains several sections that will aid the NIH admission committee's identification and evaluation of each graduate student. Specific areas required to evaluate a candidate include the following: contact information, citizenship status, identification of programs to which the student wishes to apply, students' graduate university information and undergraduate university information, standardized examination scores, references and letters of recommendation, proposed NIH advisor information, University advisor information, research interests, career goals, and proposed research in NIH IRP. Ethnicity and gender are additional optional information used to evaluate the GPP recruiting abilities and compliance with federal regulations. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Students pursuing an advanced degree, Ph.D., and would like to perform their dissertation research in the NIH Intramural Research Program laboratories.

The annual reporting burden is displayed in the following table:

ESTIMATES OF HOUR BURDEN

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Student Application to Current Graduate Student Programs	200	1	0.50	100
Student Application to Future Graduate Student Programs	400	1	0.50	200
Recommendations (600 × 3)	1800	1	0.25	450
Totals	2400			750

Estimate of Capital Costs, Operating Costs, and/or Maintenance Costs are displayed in the following table:

ESTIMATE OF ANNUAL COST TO THE FEDERAL GOVERNMENT

Annualized capital, start-up cost	Amount (dollars)	Operational/maintenance & purchase components	Amount (dollars)
Information Collection	0.00	Trouble-shooting and monitoring fees	2,000.00
Aplication Design, Development, Testing	12,000.00	Maintenance	1,000.00
Total	12,000.00	Total	$3,000.00

Estimate of Other Total Annual Cost Burden: $15,000.00.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Patty McCarthy, Program Coordinator, Graduate Partnerships Program, National Institutes of Health, 10 Center Drive, Building 10/Room 1C129, Bethesda, Maryland 20892–1153, or call 301–594–9603 or e-mail your request, including your address to: *mccarthy@od.nih.gov*.