

Hampshire Ave., Bldg. 22, rm. 6478, Silver Spring, MD 20993-0002, 301-796-0700; or

Toni Stifano, Center for Biologics Evaluation and Research (HFM-600), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims." The term "PRO" refers to one or more concepts about how patients feel or function as perceived and reported by study subjects (*i.e.*, "patients"). PROs may represent traditional aspects of health such as symptoms and activities of daily living, or broader concepts such as physical function, well-being related to health, and satisfaction with treatment. "PRO instruments" are the tools for measuring PROs.

Generally, sponsors can use study results measured by PRO instruments to support claims in approved product labeling if the claims are derived from adequate and well-controlled investigations using PRO instruments that reliably and validly measure the specific concepts claimed. The amount of evidence expected to support a labeling claim measured by a PRO instrument is the same as that required for any other labeling claim. As with other labeling claims, the determination of whether the endpoint is an adequate measure of effectiveness is specific to the intended population, the characteristics of the condition or disease treated, and the sensitivity of the clinical study used to measure the endpoint.

This draft guidance presents our current thinking on the review process concerning the development, validation, and application of PRO instruments in the clinical study setting.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on patient-reported outcome measures. It does not create or confer any rights for or on any person and does 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 regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: January 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for AMARYL (glimepiride), MOBIC (meloxicam), NORVIR (ritonavir), and NOVOLOG (insulin aspart). These summaries are being made available consistent with the Best Pharmaceuticals for Children Act (the BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

ADDRESSES: Submit written requests for single copies of the summaries to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

FOR FURTHER INFORMATION CONTACT:

Grace Carmouze, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 1613, Silver Spring, MD 20993-0002, 301-796-2200, e-mail: carmouzeg@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for AMARYL (glimepiride), MOBIC (meloxicam), NORVIR (ritonavir), and NOVOLOG (insulin aspart). The summaries are being made available consistent with section 9 of the BPCA (Pub. L. 107-109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet at <http://www.fda.gov/cder/pediatric/index.htm>, summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for AMARYL (glimepiride), MOBIC (meloxicam), NORVIR (ritonavir), and NOVOLOG (insulin aspart). Copies are also available by mail (see **ADDRESSES**).

II. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/pediatric/index.htm>.

Dated: January 27, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-1435 Filed 2-2-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Tobacco Use Supplement to the Current Population Survey Series: 2006-2007 Tobacco Use Supplement to the Current Population Survey

SUMMARY: Under the provisions of Section 3507(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 1, 2005, page 65906 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comments. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised or

implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Tobacco Use Supplement to the Current Population Survey Series: 2006-2007 Tobacco Use Supplement to the Current Population Survey.

Type of information request: Reinstatement With Change of OMB #0925-0368, Expiration 01/31/2004.

Need and Use of Information Collection: The 2006-2007 Tobacco Use Supplement to the Current Population Survey conducted by the Census Bureau will collect data from the civilian non-institutionalized population on tobacco use, smoking prevalence and attempts at cessation; workplace smoking policies; health professional advice to stop smoking; and changes in smoking norms and attitudes. This survey will provide invaluable information to government agencies and departments, other scientists and the general public necessary for tobacco control research, as well as measure progress toward tobacco control as part of the National Cancer Institute's (NCI's) Cancer Progress Report, and the Department of Health and Human Services' Healthy People 2010 Goals. It is also relevant to past reports of NCI plans for the National Investment in Cancer Research and NCI's long term strategic plan for eliminating the suffering and death due to cancer. This survey is part of a continuing series of surveys that were

sponsored by NCI and fielded periodically over the 1990's by the Census Bureau as part of the American Stop Smoking Intervention Study for Cancer Prevention (ASSIST) project (OMB #0925-0368, exp. 01/31/01, 12/31/99, 03/31/97, 06/30/93) and made available for general public use. The Tobacco Use Supplements since 2001-02 have been fielded and will be continuing over the next decade alternating between a standard or core tobacco use survey (such as this 2006-2007 survey) and a special topic survey focusing on emerging tobacco control issues (such as the 2003 Tobacco Use Special Cessation Supplement). The survey will allow state specific estimates to be made. Data will be collected in May 2006, August 2006 and January 2007 from approximately 285,000 respondents. The National Cancer Institute is co-sponsoring this survey with the Centers for Disease Control and Prevention.

Frequency of Response: One-time study.

Affected Public: Individuals or households.

Type of Respondents: Persons 15 years of age or older. The annual reporting burden is presented in exhibit 1 below. The annualized cost to respondents is estimated at \$177,691. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

EXHIBIT 1.—ESTIMATES OF RESPONDENT HOUR BURDEN

Number of respondents (number of annual respondents)	Frequency of response	Average bur- den hours per response	Total hour burden (total annual hour burden)
285,000 (95,000)	1	0.1169	33,317 (11,106)

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited one or more of the following points: (1) 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) 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) 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 those who are to respond, including the use of appropriate automated, electronic,

mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503. Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Anne Hartman, M.S., M.A., Health Statistician, National Cancer Institute, 6130 Executive Blvd—MSC 7344,

Executive Plaza North, Suite 4005, Bethesda, Maryland 20892-7344, or call non-toll free (301) 496-4970, or FAX your request, to (301) 435-3710, or E-mail your request, including your address, to ah42t@nih.gov or Anne_Hartman@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: January 27, 2006.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

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