II. Process

The process of rescinding, revising, and reissuing all of the existing Information Sheets (there are approximately 40) may take several years to complete. The agency plans to make the process as transparent as possible. Therefore, FDA advises users to periodically check the agency's Information Sheet Web page at *http://www.fda.gov/oc/gcp/guidance.html*, throughout this time period. As guidances are revised and reissued and as new guidances are developed, they will be made available according to the GGP process and on this Web site.

III. Guidances Being Made Available With This Notice

The agency is announcing the availability of the following five Information Sheet Guidances that have been revised. These five Information Sheet Guidances replace the Information Sheets of the same titles (unless otherwise indicated) published in 1998.

- ''FDA Inspections of Clinical Investigators'' (previously entitled ''FDA Clinical Investigator Inspections''): This guidance is intended to provide information about FDA's inspections of clinical investigators conducted under FDA's Bioresearch Monitoring Program.
- ''FDA Institutional Review Board Inspections'': This guidance is intended to provide information about FDA's inspections of IRBs conducted under FDA's Bioresearch Monitoring Program.
- ''Waiver of IRB Requirements for Drug and Biologic Studies'' (previously entitled ''Waiver of IRB Requirements''): This guidance is intended to provide information about sponsor and sponsor-investigator requests for waivers of IRB requirements for drug and biologic studies.
- ''Significant Risk and Nonsignificant Risk Medical Device Studies'': This guidance is intended to provide advice to sponsors, clinical investigators, and IRBs on how to determine the differences between significant risk and nonsignificant risk medical device studies.
- ''Frequently Asked Questions About Medical Devices'' (previously entitled ''Medical Devices; Frequently Asked Questions about IRB Review of Medical Devices; Emergency Use of Unapproved Medical Devices''): This guidance is intended to assist sponsors, clinical investigators, and IRBs by answering common questions FDA receives concerning medical devices.

These Information Sheet Guidances are level 2 guidances according to FDA's GGPs regulation. FDA is implementing the guidances immediately without prior public comment because they contain only minor revisions to reflect current policy and/or are consistent with policy interpretations of the Department of Health and Human Service's Office for Human Research Protections. These Information Sheet Guidances represent the agency's current thinking on topics concerned with human subject protection. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public.

IV. Comments

As with all FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to the Information Sheet Guidances or suggest topics for new Information Sheet Guidance. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on these Information Sheet Guidances.

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. The guidances and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/oc/gcp/guidance.html*.

Dated: January 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1476 Filed 2–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0044]

Draft Guidance for Industry on Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (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 draft guidance was prepared by the Office of New Drugs and the Office of Medical Policy in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Center for Devices and Radiological Health (CDRH) at FDA. This document provides guidance to industry on the measurement of patient-reported outcomes (PROs) in studies to support medical product claims in approved labeling. The draft guidance describes how FDA evaluates PRO instruments used as effectiveness endpoints in clinical trials. It also describes our current thinking on how sponsors can develop and use PRO instruments to support claims in approved product labeling. By explicitly addressing the review issues identified in this guidance, sponsors can increase the efficiency of their endpoint discussions with FDA during the product development process, streamline FDA's review of PRO endpoint adequacy, and provide optimal information about the patient's perspective of treatment benefit at the time of product approval.

DATES: Submit written or electronic comments on the draft guidance by April 4, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance can also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Laurie B. Burke, Center for Drug Evaluation and Research (6411), Food and Drug Administration, 10903 New

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.

[FR Doc. E6–1433 Filed 2–2–06; 8:45 am]

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*.