

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action." This draft guidance provides recommendations to applicants planning product quality studies to document BA or BE in support of NDAs or ANDAs for locally acting drugs in nasal aerosols and nasal sprays. This guidance addresses BA and BE studies of prescription corticosteroids, antihistamines, anticholinergic drug products, and the over-the-counter (OTC) mast-cell stabilizer cromolyn sodium. The guidance does not address studies of nasal sprays included in applicable OTC monographs or studies of: (1) Metered-dose products intended to deliver drugs systemically via the nasal route, or (2) drugs in nasal nonmetered dose atomizer (squeeze) bottles that require premarket approval.

Because many substantive changes were made to the guidance after it issued in 1999, the guidance is being reissued at this time for comment as a level 1 draft guidance. We encourage applicants to submit any evidence that supports or refutes the approaches outlined in this guidance to the docket number given in brackets in the heading of this document.

The changes made were based on the following: (1) Public comments submitted to the original docket, (2) the outcome of April 2000 and July 2001 meetings of the Orally Inhaled and Nasal Drug Products Subcommittee of the FDA Advisory Committee for Pharmaceutical Science (ACPS), (3) a July 2001 meeting of the ACPS, and (4) internal discussions within the Center for Drug Evaluation and Research. Changes include reduction in the recommended extent of in vitro testing, elimination of two of the three options for rhinitis study design, and elimination of the recommendation to demonstrate a dose-response relationship from the recommended rhinitis study design (traditional 2-week study). The latter two changes are based on ACPS recommendations. A section on reserve samples for BA and BE testing has also been added. The statistical information that was previously part of the original draft has now been consolidated into appendices that will be published at a later date.

This level 1 draft guidance is being issued consistent with FDA's good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 The draft guidance, when finalized, will represent the agency's current thinking on BA and BE product quality information related to nasal inhalation aerosols and nasal metered-dose spray pumps. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Alternative approaches to documentation of BA and BE may be used if such approaches satisfy the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch 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 either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

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Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for

review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Uniform Progress Report (UPR) for HRSA Continuation Training Grants (OMB No. 0915-0061)—Revision

The HRSA Progress Reports for Continuation Training Grants are used for the preparation and submission of continuation applications for Titles VII and VIII health professions and nursing education and training programs. The Uniform Progress Report measures grantee success in meeting (1) the objectives of the grant project and (2) the cross-cutting outcomes developed for the Bureau's education and training programs. Part I of the progress report is designed to collect information to determine whether sufficient progress has been made on the approved project objectives, as grantees must demonstrate satisfactory progress to warrant continuation of funding. Part II collects information on activities specific to a given program. Part III, Comprehensive Performance Management System, collects data on overall project performance related to the Bureau of Health Professions' strategic goals, objectives, outcomes and indicators. Progress will be measured based on the objectives of the grant project and outcome measures and indicators developed by the Bureau to meet requirements of the Government Performance and Results Act (GPRA).

To respond to the requirements of GPRA, the Bureau developed goals, outcomes and indicators that provide a framework for collection of outcome data for its Titles VII and VIII programs. An outcome-based performance system is critical for measuring whether program support is meeting national health workforce objectives. At the core of the performance measurement system are found cross-cutting goals with respect to workforce quality, supply, diversity and distribution of the health professions workforce. A demonstration project to assess availability of the data needed to support the indicators was conducted, and data from this project are currently being analyzed.

The grantees were able to obtain and submit progress reports electronically for fiscal year 2001.

The burden estimate is as follows: