DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1335]

Draft Guidance for Industry on Allergic Rhinitis: Clinical Development Programs for Drug Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Allergic Rhinitis: Clinical Development Programs for Drug Products.'' This draft guidance is intended to assist sponsors of new drug applications (NDA's) in designing development programs for oral and intranasal drug products for the treatment of allergic rhinitis in children and adults.

DATES: Submit written comments on the draft guidance by September 19, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Martin H. Himmel, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Allergic Rhinitis: Clinical Development Programs for Drug Products.'' Information about the pathophysiology and treatment of allergic rhinitis and its subtypes, seasonal allergic rhinitis (SAR), and perennial allergic rhinitis (PAR) has grown markedly in the past decade. The recommendations in this draft guidance are based on a careful assessment of important issues raised in the review of both adult and pediatric allergic rhinitis clinical trials and the agency's current understanding of the mechanism of the two related disorders of SAR and PAR. The draft guidance addresses issues of study design, data analysis, evaluation, and overall considerations for pediatric and adult trials.

This draft guidance includes recommendations on patient selection, inclusion and exclusion criteria, choice of primary and secondary endpoints, statistical analysis, safety monitoring, evaluation of the onset of action, durability of effect, and prophylaxis trials. The draft guidance also discusses abbreviated development programs that may be conducted for a formulation or device change. When finalized, this draft guidance will replace the previous guidance document entitled ''Points to Consider: Clinical Development Programs for New Nasal Spray Formulations'' (January 1996).

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on development programs for oral and intranasal drug products for the treatment of allergic rhinitis in children and adults. 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 statute, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1306]

Draft Guidance for Industry on the Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics; 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 ''Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics.'' The agency has initiated a comprehensive effort to improve the content and format of prescription drug labeling. This draft guidance is the first in a series of guidance documents on the content and format of individual labeling sections. FDA intends to carefully coordinate development and implementation of these various labeling initiatives to minimize the potential burden for manufacturers and other affected parties.

DATES: Submit written comments on the draft guidance by September 19, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or at http://www.fda.gov/cber/guidelines.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to 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, 301–827–3844, FAX 888–CBERFAX, or Voice Information System at 800–835–4709. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janet M. Jones, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration,

5600 Fishers Lane, Rockville, MD 20857, 301–594–6758, or

Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190, e-mail: stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION: As part of a comprehensive effort to make prescription drugs safer to use, FDA is engaged in several initiatives to make prescription drug labeling a better information source for health care practitioners—clearer, more informative, more accessible, and more consistent from drug to drug. FDA is developing and intends to publish a proposed rule to revise the overall format of prescription drug labeling. It will propose reordering the sections of the labeling, based on the importance of the information to practitioners, and the frequency with which practitioners refer to a section and creating a ''highlights'' section and an index.

FDA also is working on a proposed rule to revise the current requirements for the pregnancy subsection of labeling (see 62 FR 41061, July 31, 1997, announcing 21 CFR part 15 hearing to discuss the category requirements, and 64 FR 23340, April 30, 1999, announcing a public advisory committee meeting to discuss possible changes to pregnancy labeling).

In addition, FDA is developing guidance documents that focus on the content of certain labeling sections. The draft guidance on ''Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics'' provides guidance on, among other things, criteria for including adverse reactions in labeling, presentation of adverse reactions in a table, and organization of the section. This section exists in the current labeling and is expected to continue to exist when the new format for prescription drug labeling is proposed.

At this time, FDA also is developing guidances for the Clinical Pharmacology, Clinical Studies, and Warnings/Precautions sections. The agency expects to publish these draft guidances for comment in the coming months. To date, the agency has focused its efforts on these sections because they typically contain large amounts of important and complex information and there have been significant variations in their format and content across different medical products. Guidances for other labeling sections may be developed later.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on the content and format of the adverse reactions section of labeling for human prescription drugs and biologics. 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 statute, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1336]

Draft Guidance for Industry: Pediatric Oncology Studies in Response to a Written Request; 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 ''Pediatric Oncology Studies in Response to a Written Request.'' The draft guidance document provides assistance to applicants intending to respond to a written request from FDA for pediatric studies for a drug that may show potential health benefits in children with cancer. The draft guidance discusses the kind of information applicants should include in their pediatric studies, which, if responsive to a written request, may make the applicant's drug eligible to qualify for an additional 6 months of marketing exclusivity. This guidance is part of the agency's pediatric initiative to generate new knowledge to assist practitioners in the care of children with cancer and to help provide pediatric patients early access to emerging new drugs.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by September 18, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of ''Pediatric Oncology Studies in Response to a Written Request'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Manufacturers Assistance and Communications Staff (HFM–42), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 208521448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Terrie L. Crescenzi, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, FAX 301–827–2520, e-mail: crescenzit@cder.fda.gov, or

Elaine C. Esber, Center for Biologics Evaluation and Research (HFM–30), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0641, FAX 301–827–0644, e-mail: esber@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pediatric Oncology Studies in Response to a Written Request.'' Section 111 of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act), signed into law by President Clinton on November 21, 1997, created section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a), which permits certain marketing applications to obtain an additional 6 months of marketing exclusivity if the sponsor submits requested information