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Draft Guidance for Industry on Allergic Rhinitis: Clinical Development Programs for Drug Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Allergic Rhinitis: Clinical Development Programs for Drug Products.'' This draft guidance is intended to assist sponsors of new drug applications (NDA's) in designing development programs for oral and intranasal drug products for the treatment of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DATES: Submit written comments on the draft guidance by September 19, 2000.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ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Allergic Rhinitis: Clinical Development Programs for Drug Products.''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 The recommendations in this draft guidance are based on a careful assessment of important issues raised in the review of both adult and pediatric allergic rhinitis clinical trials and the agency's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 The draft guidance addresses issues of study design, data analysis, evaluation, and overall considerations for pediatric and adult trials.

This draft guidance includes recommendations on patient selection, inclusion and exclusion criteria, choice of primary and secondary endpoints, statistical analysis, safety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,