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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D-0067]

Guidance for Industry on Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA).” This guidance is intended to assist developers of drugs, biological products, or medical devices intended for the treatment of rheumatoid arthritis (RA). It provides guidance on the types of claims that could be considered for such products and on clinical evaluation programs that could support those claims. The guidance also contains recommendations on the timing, design, and conduct of preclinical and clinical trials for RA products and on special considerations for juvenile RA.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the guidance are available on the Internet at “<http://www.fda.gov/cder/guidance/index.htm>”, or “<http://www.fda.gov/cber/guidelines.htm>”. Submit written requests for single copies of the guidance for industry to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Call 888-CBERFAX or 301-827-3844 for copies by fax or CBER’s Voice Information System at 800-835-4709 or 301-827-1800 for copies by

mail. Send one self-addressed adhesive label to assist the offices in processing your requests.

Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Kent R. Johnson, Center for Drug Evaluation and Research (HFD-550), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2080; or

Jeffrey N. Siegel, Center for Biologics Evaluation and Research (HFM-582), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5094; or

Sahar M. Dawisha, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3091, ext. 196, FAX 301-594-2358.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled “Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA).” The guidance contains recommendations on the timing, design, and conduct of preclinical and clinical trials for RA products and on special considerations for juvenile RA.

This guidance has been under development since 1995. The first version of the guidance was completed in March 1996. An additional section on juvenile RA was added in May of that year. A second version was completed in January 1997. Two public workshops have been held on the topic, on March 27, 1996, and on July 23, 1996. On February 5, 1997, the draft guidance was discussed at a meeting of the Arthritis Advisory Committee. Another draft version, published for comment on March 18, 1998 (63 FR 13259), incorporated suggestions made during the February 5, 1997, Arthritis Advisory Committee. In developing this final version of the guidance, FDA considered comments submitted to the docket on the March 18, 1998, draft guidance.

This guidance represents the agency’s current thinking on RA. 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, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests are to be identified with the docket

number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 10 1999

February 10, 1999



William K. Hubbard
Associate Commissioner for Policy Coordination

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