from approving a subsequently filed ANDA containing a paragraph IV certification.

Pediatric exclusivity was created by the passage of the Food and Drug Administration Modernization Act, enacted on November 21, 1997. This provision, contained in section 505A of the act, provides an incentive for innovator companies to perform and submit to the agency pediatric studies that may produce health benefits in the pediatric population. This benefit is available to a new drug application holder for the submission of pediatric studies in response to a written request issued by the agency. Pediatric exclusivity extends for 6 months existing patent and/or exclusivity protection on the innovator drug and begins to run on the date the existing patent and/or exclusivity protection on the innovator drug would otherwise expire. ANDAs referencing the innovator drug may not be approved during the pediatric exclusivity period.

FDA seeks public comment on whether pediatric exclusivity runs concurrently or consecutively with 180-day generic drug exclusivity when a favorable court decision in a paragraph IV patent challenge lawsuit is issued less than 180 days before the beginning of or during the pediatric exclusivity period.

II. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments by June 20, 2001. 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 14, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12615 Filed 5–15–01; 4:12 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0197]

Clinical Development Programs for Drugs, Biological Products, and Devices for the Treatment of Ankylosing Spondylitis (AS) and Related Disorders; Request for Assistance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting assistance in developing guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders. Once finalized, the guidance would aid sponsors and others interested in developing new agents to treat AS and related disorders.

Before the agency can develop such guidance, a critical appraisal of certain fundamentals of the science related to AS is needed. FDA is interested specifically in identifying a party, or parties, willing to take the lead in coordinating this critical appraisal.

DATES: Submit written comments on this notice by July 20, 2001.

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

FOR FURTHER INFORMATION CONTACT: Mary Jane Walling, Center for Drug Evaluation and Research (HFD–105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2268.

SUPPLEMENTARY INFORMATION: Because of the positive response to the agency's guidance on rheumatoid arthritis, the agency has recognized the need for more information on the development of drugs, biological products, and devices for the treatment of AS and related disorders. FDA intends to put the information received in response to this notice in a public docket so that interested parties can learn of each other and coordinate these activities.

Specifically, the agency is interested in identifying an interested group or consortium of interested groups from academia, industry, practitioners, and patients and their representatives willing to take the lead in a critical appraisal of certain fundamentals of the science related to AS. Initially, the parties may want to organize a public meeting to discuss relevant questions (a number of which are noted below). The agency hopes this meeting will lead to conceptual advances now not present and their expression in a series of concept papers. Subsequent workshops would then be able to fully discuss these concept papers, soliciting feedback from all quarters including regulators from the United States and elsewhere. Emphasis should be on debating the rationale for various approaches to key issues. The agency welcomes other suggestions of activities that could be undertaken as part of this guidance development effort.

To provide a starting point for discussion, the agency has developed a list of some key concepts that the interested parties may want to consider at the meeting:

1. Scope: Should the guidance discuss AS alone, or a broader spondyloarthropathy rubric? What about the clinical subgroups and pediatric expressions of the disorder(s)?

2. Claims: What type of claims structure is optimal to encompass the types of clinical benefit a therapeutic product might have on patients with AS? What type of evidence would be needed to support each proposed claim?

3. Measures of disease activity: Are currently available instruments for measuring disease activity adequate or are new measures required? Which disease activity should be measured in clinical trials in AS, and on what basis: (1) A consensus approach, which aims for agreement (clinicians, patients, and others) based on a blend of an observer-driven approach and performance characteristics; (2) a decision based on the comparative statistical characteristics of each measurement using concepts such as random measurement error; or (3) a fully data-driven approach where each measurement is tested in a standard venue to assess its predictive capacity.

4. Overall trial design: Are longitudinal comparison of means optimal? Because longer trials inevitably have substantial dropouts, would a survival analysis be more appropriate?

5. Intrinsic trial design: Which measures should be included in the primary analysis of the clinical trial to assess whether the therapeutic product is associated with a clinical benefit? Do all measures need equal-weight in the primary analysis? Can they be unequally weighted? Is the use of composites justified? Are outcomes of secondary endpoints essential for determining the success of the trial?

Interested persons should submit to the Dockets Management Branch (address above) comments and

expressions of interest in taking a lead in a critical appraisal. 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. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 11, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12625 Filed 5–18–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0193]

Medical Devices Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers.'' This draft guidance document provides specific recommendations on data and information medical device manufacturers should submit in premarket notifications (510(k)s) for biological indicators intended to monitor sterilizers used in health care facilities. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written comments on the draft guidance by August 20, 2001.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this 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 for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

FDA regulates biological indicators intended to monitor sterilizers used in health care facilities as class II medical devices, requiring premarket notification (510(k)). The effective performance of sterilizers used in health care facilities is important to prevent nosocomial infections. Biological indicators provide users with information on the effectiveness of the sterilization process. This draft guidance document recommends the kind of data and information you should submit in a 510(k) for these devices. The use of comprehensive, scientifically sound review criteria helps ensure the safety and effectiveness of these devices. FDA recognizes that providing FDA reviewers, 510(k) applicants, and other interested parties information on its review process can promote a consistent and efficient regulatory process.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on premarket notifications (510(k)) for biological indicators intended to monitor sterilizers used in health care facilities. 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 applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document is issued as a Level 1 guidance consistent with the GGP regulations.

III. Electronic Access

In order to receive ''Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1320) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers'' is also available at http://www.fda.gov/cdrh/ode/guidance/1320.pdf. Guidance documents are also available on the Dockets Management Branch Web site at http://www.fda.gov/ohrms/dockets/default.htm.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by August 20, 2001. Submit two copies of any comments, 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 document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 8, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–12624 Filed 5–18–01; 8:45 am]

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