

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0033]

DDM

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Certifier A Corbin

Establishing a Docket for the Factor VIII Inhibitor Public Workshop;

Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a docket to receive information and comments on the November 21, 2003, public workshop entitled "Factor VIII Inhibitors" (the workshop). We are opening the docket because there was insufficient time available during the workshop for a full discussion of the many important topics covered at the workshop.

DATES: Submit written or electronic comments on the workshop, related regulatory and scientific issues, and comments on information submitted to the docket by other interested parties by *[insert date 18 months after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments and information related to the workshop to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852-1448. Submit electronic comments or information to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic and other access to the slide presentations and transcript from the workshop.

FOR FURTHER INFORMATION CONTACT: Sharon Carayiannis, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 20, 2003 (68 FR 59942), we published a notice to announce a public workshop entitled "Factor VIII Inhibitors." On November 21, 2003, we, in cosponsorship with the International Association for Biologicals, held the workshop to address regulatory and scientific concerns about inhibitors to Factor VIII induced by Antihemophilic Factor (Factor VIII) products. These inhibitors arise in a significant minority of patients with hemophilia and make replacement therapy problematic. The workshop covered a broad range of topics. The workshop provided valuable information, but additional time was needed at the close of the meeting for continued dialogue on important topics. At the end of the workshop, we invited written comments to provide an opportunity for a full discussion of issues.

We have established this docket to encourage interested parties to continue to provide information about Factor VIII inhibitors, comments on the workshop, and comments on information submitted to the docket by other interested parties. We also request that those who have already submitted written comments and information to FDA resubmit the same comments to the docket to ensure their adequate consideration since this information was not previously submitted to the docket. We also posted this request for comments and information at <http://www.fda.gov/cber/meetings/fctrvIII112103L.htm>.

Comments submitted to the docket will assist us in determining the need for and feasibility of establishing new inhibitor assay standards and methodologies, stakeholders' opinions about current upper and lower limits of acceptable inhibitor formation in clinical trials, and the use of plasma-derived versus recombinant Factor VIII controls in pharmacokinetic trials, among other issues. We may also consider the information in preparing any future guidance on clinical trials to evaluate potential inhibitor formation from Factor VIII products.

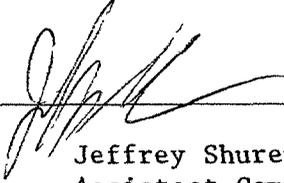
II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the workshop. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of this notice, the slide presentations and transcript from the workshop, and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the slide presentations at <http://www.fda.gov/cber/summaries.htm> and the transcript of the workshop at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: 6/24/04
June 24, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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