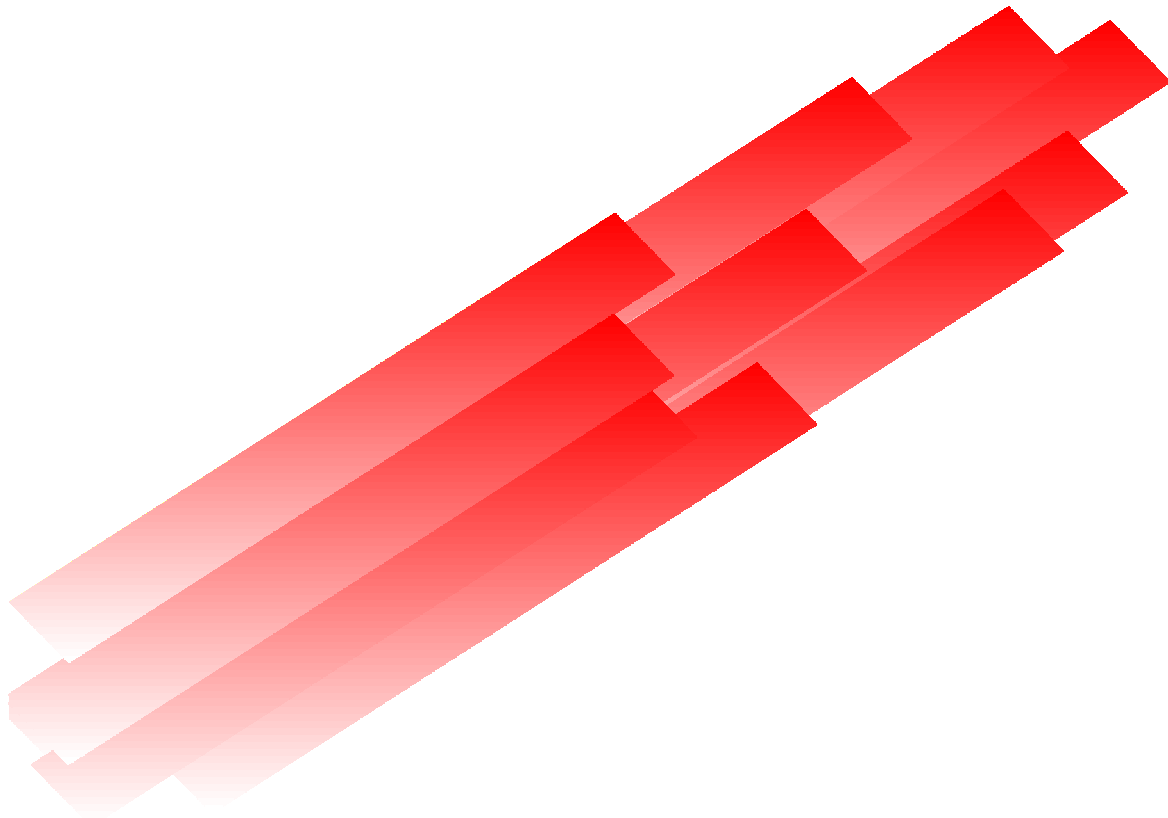


Guidance for Industry

Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
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Procedural Guidance 4**

Guidance for Industry Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements

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After the comment period closes, comments should be provided in writing to the Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448.

Additional copies are available from:

*The Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER),
5600 Fishers Lane, Rockville, MD 20857 (Tel) 301-827-4573
<http://www.fda.gov/cder/guidance/index.htm>*

or

*Office of Communication, Training, and Manufacturers Assistance (HFM-40),
Center for Biologics Evaluation and Research (CBER)
1401 Rockville Pike, Rockville, MD 20852-1448,
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GUIDANCE FOR INDUSTRY¹

Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements

I. INTRODUCTION

Section 403(a) of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) requires that FDA “publish in the *Federal Register* standards for the prompt review of supplemental applications submitted for approved articles” The legislative history indicates that this provision was directed at certain types of efficacy supplements (i.e., supplemental applications proposing to add a new use of an approved drug to the product labeling).² Section 403(b)(3) of the Modernization Act requires that FDA provide guidance to “define supplemental applications that are eligible for priority review.” This guidance fulfills both Modernization Act requirements.

II. STANDARDS FOR THE PROMPT REVIEW OF EFFICACY SUPPLEMENTS

Section 101 of the Modernization Act reauthorized for an additional five years, with certain technical changes, the user fee program described in the Prescription Drug User Fee Act of 1992. Section 101 directed that the user fees authorized by the amendments in that subtitle “be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the [performance] goals identified . . . in the letters from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate, as set forth in the Congressional Record.” The referenced performance goals include standards for the review of all efficacy supplements (including those proposing to add a new use of an approved drug to the product labeling) as follows:

¹This guidance has been prepared by the Review Management Working Group comprising individuals in the Centers for Drug Evaluation and Research (CDER) and Biologics Evaluation and Research (CBER) at the Food and Drug Administration. This guidance document represents the Agency’s current thinking on the standards for the prompt review of efficacy supplements. 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.

² See U.S. Congress, Senate Committee on Labor and Human Resources, *Food and Drug Administration Modernization Act of 1997*, S. Rept. 105-43 on S. 830, pp.41-42, 105th Cong., 1st sess., 1 July 1997; and House Committee on Commerce, *Prescription Drug User Fee Reauthorization and Drug Regulation Act of 1997*, H. Rept. 105-310 on H.R. 1411, pp. 63-64, 105th Cong., 1st sess., 7 October 1997.

Fiscal Year 1998:

Standard Efficacy Supplements - 90% of reviews to be completed within 12 months
Priority Efficacy Supplements - 90% of reviews to be completed within 6 months

Fiscal Year 1999

Standard Efficacy Supplements - 30% of reviews to be completed within 10 months
90% of reviews to be completed within 12 months
Priority Efficacy Supplements - 90% of reviews to be completed within 6 months

Fiscal Year 2000

Standard Efficacy Supplements - 50% of reviews to be completed within 10 months
90% of reviews to be completed within 12 months
Priority Efficacy Supplements - 90% of reviews to be completed within 6 months

Fiscal Year 2001

Standard Efficacy Supplements - 70% of reviews to be completed within 10 months
90% of reviews to be completed within 12 months
Priority Efficacy Supplements - 90% of reviews to be completed within 6 months

Fiscal Year 2002

Standard Efficacy Supplements - 90% of reviews to be completed within 10 months
Priority Efficacy Supplements - 90% of reviews to be completed within 6 months

The Agency intends to use these performance goals to fulfill the requirement of the Modernization Act that it establish standards for the prompt review of efficacy supplements.

III. DEFINITION OF SUPPLEMENTS ELIGIBLE FOR PRIORITY REVIEW

Both the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have previously established the criteria used to designate original and supplemental applications as appropriate for priority review, and these criteria were used in the implementation of the Prescription Drug User Fee Act of 1992. CDER's policy specifies, in relevant part, that an application or supplement for a drug product will receive a priority review if the product, if approved "would be a significant improvement, compared to marketed products, including non-drug products/therapies in the treatment, diagnosis, or prevention of a disease."³

³ CDER Manual of Policies and Procedures, 6020.3 - Priority Review Policy.

CBER's standard operating procedures specify that a biological product original or supplemental application will receive priority review if the product, if approved, "would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease."⁴

These criteria and definitions are being used currently by the Agency to determine whether an efficacy supplement is eligible for priority review.

⁴ CBER Standard Operating Procedures and Policy Manual, 8405.