4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0196]

Food and Drug Administration Prescription Drug User Fee Act V Benefit-Risk Plan; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft 5-year plan describing the Agency's approach to further developing and implementing a structured framework for benefit-risk assessment in the human drug and biologic review process and the opportunity for public comment on the draft plan. This plan is part of FDA's commitments that were made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). FDA has published the draft plan on its Web site at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA), (Public Law 112-144). Section 905 of FDASIA amends section 505(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by requiring FDA to "implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs."

Title I of FDASIA reauthorizes PDUFA and provides FDA with the user fee resources necessary to maintain an efficient review process for human drug and biological products. The reauthorization of PDUFA includes performance goals and procedures for the Agency that represent FDA's commitments during fiscal years 2013-2017. These commitments are fully described in the document entitled "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017" ("PDUFA Goals Document"), available on FDA's Web site at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf. Section X of the PDUFA Goals Document, titled "Enhancing Benefit-Risk Assessment in Regulatory Decisionmaking," addresses the development of a 5-year plan that describes the Agency's approach to further develop and implement a structured benefit-risk framework in its human drug and biologic review process. The publication and implementation of this plan are intended to fulfill the requirement in section 905 of FDASIA and the commitments described in Section X of the PDUFA Goals Document.

II. Draft Plan Describing Structured Approach to Benefit-Risk Assessment

Ensuring the safety, effectiveness, and quality of human drugs is a complicated regulatory task, requiring FDA's consideration of a multitude of complex factors. FDA's regulatory decision making process takes into consideration not only the data submitted in a marketing application, but also a broad set of additional factors, including the clinical context for the proposed product (such as the nature and severity of the disease or condition that the proposed product is intended to treat or prevent and the benefits and risks of other available therapies for that disease or condition) and any risk management tools that might be necessary to ensure that the benefits of the proposed product outweigh its risks.

FDA believes that implementing a standardized structure for the analysis of the various benefit and risk considerations that make up a regulatory decision will help to facilitate balanced and consistent consideration of the benefit and risk factors during the review process and to enhance the transparency of regulatory review. FDA therefore has developed a draft plan describing a benefit-risk assessment framework that is designed to make explicit the consideration of the various benefit-risk factors and the role of those factors in the regulatory decision-making process for human drug and biological product marketing applications. It is important to note that, as specified in section 905 of FDASIA, this framework does not change the criteria for approval of a drug or biological product. All new drug applications and biological license applications must meet the requirements for approval under the FD&C Act and the Public Health Service Act, respectively.

By clearly articulating FDA's key considerations in a standard structure, this framework can serve as an important tool for the analysis and discussion of the relevant benefit and risk considerations during the review process. A second and equally important purpose of the benefit-risk framework is that it can serve as a tool to communicate the reasoning of FDA's regulatory decisions to the public. When FDA approves a new drug or biological product, it generally posts decisional memos on the Agency's Web site. These documents may be highly technical and may not be easily understandable to a broad audience with varying backgrounds. The benefit-risk framework aims to enhance FDA's communication of its decisions by making clear the important considerations in the Agency's decision-making process, and how they affected the final regulatory decision, in a clear, succinct summary.

With this notice, FDA is announcing the availability of a draft 5-year plan describing the Agency's approach to further developing and implementing the benefit-risk framework and the opportunity for the public to comment on the plan. FDA has published the plan on the Agency's

Web site at

http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf.

The comment period will remain open for 60 days following the publication of this notice. After consideration of public comments, FDA will finalize the plan. Throughout PDUFA V, the Agency will update the plan as necessary and post all updates on the FDA's Web site.

Dated: March 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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