FDA Finalizes Policy on Labeling for Drugs Approved Under Accelerated Approval

The accelerated approval pathway facilitates earlier approval of drugs that treat serious conditions.

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FDA In Brief: FDA finalizes policy on labeling for drugs approved under accelerated approval, reflecting the more frequent use of this pathway for drugs used in certain clinical settings

“The FDA is committed to making sure that health care providers have accurate, actionable information about prescription medications, so that patients and providers can make the most informed decisions about a medicine’s risks and benefits. The accelerated approval pathway facilitates earlier approval of drugs that treat serious conditions, taking into account a lack of alternative treatments. Since the pathway’s inception, the clinical community has garnered a greater understanding of how certain surrogate endpoints, used in the setting of accelerated approval, inform clinical practice. This is especially true in the field of oncology. Today, to make sure this pathway remains robust, we’re taking new steps to help ensure that a product’s labeling provides actionable and complete information about the clinical evidence supporting an accelerated approval and clearly states that post-market commitments may have to be met for an indication to remain approved. In certain circumstances, it may be adequate for sponsors simply to include the endpoint used to support approval in the indications section of the labeling, and then include additional information about the evidence in the clinical studies section. Reporting the endpoint used may convey sufficient information about uncertainty regarding the limitations of the usefulness of the drug and of uncertainty about its anticipated clinical benefits. We’re also providing labeling recommendations for the circumstances when approval of a drug or indication approved under accelerated approval may be withdrawn because it fails to demonstrate clinical benefit in post-market, confirmatory trials,” said FDA Commissioner Scott Gottlieb, MD. “Situations where approval may be withdrawn include those where the applicant fails to conduct any required post-marketing study with due diligence. As more drugs are being approved under the accelerated approval pathway and we make more robust use of accelerated approval as a way to advance promising medicines for serious diseases, it’s important that we update our regulatory recommendations for how these products are labeled.”

Today the U.S. Food and Drug Administration issued the final guidance, Labeling for Human

Prescription Drug and Biological Products Approved Under the Accelerated Approval Pathway, that aims to assist sponsors of drug and biological products in developing the Indications and Usage section of product labeling for products approved under the accelerated approval pathway.

The accelerated approval pathway is one of several approaches used by the FDA to expedite the development of drugs for serious or life-threatening diseases and conditions. The FDA may grant accelerated approval to a product for a serious or life-threatening disease or condition upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. This guidance focuses on how accelerated approval is represented in the Indications and Usage section of product labeling and offers recommendations to sponsors on language that best conveys different circumstances specific to accelerated approval.

During this period without a FY19 appropriation for the FDA, the agency has been focused on making sure it continues critical aspects of our work, to the extent permitted by law. At this time, for products covered by a user fee program, our review of existing medical product applications and associated policy development regarding FDA review is funded by limited carryover user fee balances. The FDA will continue to update the public on how we’re approaching our work.

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