AN OVERVIEW OF THE US FOOD AND DRUG ADMINISTRATION'S LEGISLATIVE GOALS (PART I)

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US Policy and Regulatory Alert

In anticipation of the US Food and Drug Administration (FDA) budget request for Fiscal Year (FY) 2025, this alert provides an overview of the agency's most recent priorities as outlined in FDA's FY 2024 budget, found here. This alert allows clients and stakeholders to review current year FDA priorities to indicate potential new areas of regulation and enforcement. The alert is part one of a two-part series and will be updated when the FDA releases its FY2025 priorities to identify changes in priorities from FY2024 to FY2025.

Broadly, FDA's goals aim to enhance and expand FDA's authority and oversight, as well as build upon and create new programs with regard to foods, dietary supplements, human and animal drugs, animal biologics, medical devices, and tobacco products. For example, on the food side, FDA aims to expand its Closer to Zero initiative that addresses the reduction of heavy metals in baby and young children's food products. On the drug side, FDA has proposed amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) that would significantly impact the commercial value of the 180-day exclusivity period for generic drugs. FDA also proposes several changes and amendments to the Pandemic and All-Hazards Preparedness Act (PAHPA) after the COVID-19 pandemic exposed weaknesses in the legislation as it currently exists, like FDA's ability to address medical supply chain issues.

Based on FDA's FY 2024 budget, the following information outlines FDA's goals for FY 2024, accompanied by some of the many examples of how FDA plans to accomplish each of these goals.

FOOD PRODUCTS

In FY 2024, FDA aims to:

Strengthen FDA's Authority to Protect Infants and Young Children

FDA hopes to propose amendments to the FDCA to grant FDA new authority to establish binding contamination limits in infant and young children's foods.

Create Product Testing Requirements for Foods Marketed for Consumption by Infants and Young Children

FDA would also like to propose an amendment to the FDCA that requires industry members to conduct toxic-element testing of final products marketed for infants and young children and maintain records of these test results for FDA inspection.

Modernize the Dietary Supplement Health and Education Act

FDA seeks to provide a transparent marketplace, help facilitate risk-based regulation of dietary supplements, and clarify FDA's authority over dietary supplements.

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DRUGS

In FY 2024, FDA aims to:

Amend the FDCA 180-day Exclusivity Provisions to Encourage Timely Marketing of First Generic

FDA aims to propose revisions to the FDCA to specify that 180-day patent challenge exclusivity for generic drugs does not block approval of subsequent applications from other generic drug manufacturers until a first applicant begins commercially marketing the drug.

Explicitly Address Generic Drug-Device Combination Products in the FDCA

FDA hopes to propose amendments to the FDCA to explicitly address the submission and review of Abbreviated New Drug Applications (ANDAs) for drug-device combination products, as well as drug products submitted in an ANDA that are used with a device, but which are not submitted as combination products.

Require full ingredient disclosure for drugs to promote generic competition

Create a Safe Harbor for "Skinny Labeling"

"FDA would like to create a safe harbor from patent infringement liability for human and animal generic drug applicants and 505(b)(2) applicants who market a drug with "skinny labeling."[1]

Expand Mandatory Recall Authority for All Drugs

FDA seeks to expand FDA's mandatory recall authority under the SUPPORT Act to cover all human and animal drugs.

Enhance Authority Regarding Post-Market Safety for Animal Drugs

FDA is proposing that the FDCA be amended to authorize the Center for Veterinary Medicine to require animal drug sponsors to make safety-related labeling changes based on new safety information that becomes available after approval of an animal drug.

Change Agency Regulatory Oversight Responsibility for Certain Products

FDA hopes to propose an amendment to the definition of "new animal drug" in the FDCA to provide the ability to exclude certain products or classes of products that FDA and the Environmental Protection Agency (EPA) agree are more appropriately regulated by EPA as pesticides.

Enhance Availability of Generic Animal Drugs

FDA would also like to propose amendments to the FDCA to clarify labeling requirements for generic animal drugs.

ANIMAL BIOLOGICS

In FY 2024, FDA aims to:

Enact a structured and tiered risk-based framework for animal biologic products subject to FDA regulation.

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ALL FDA-REGULATED PRODUCTS

In FY 2024, FDA aims to:

Obtain Authority to Require Destruction of Imported Products That Present a Significant Public Health Concern

FDA would like to propose amending the FDCA to give FDA the authority to require an owner or consignee to destroy any FDA-regulated product offered for import that has been refused entry and presents a significant public health concern, removing their option to export the product under the current FDCA framework.

Obtain Authority to Require Retention of Data and Records Supporting Marketed Medical Products and Product Applications and to Act Upon Submissions Containing Fraudulent or Unreliable Data

FDA wants express authority to ensure that data supporting application and nonapplication medical products are reliable and verifiable for as long as the product may be legally marketed.

TOBACCO PRODUCTS

In FY 2024, FDA aims to:

Modernize the tobacco user fees framework. FDA seeks authorization FDA to assess user fees on, and collect fees from, tobacco manufacturers and importers through a proposed FDCA amendment.

PAHPA

In FY 2024, FDA aims to:

Amend PAHPA After the COVID-19 Pandemic Exposed Weaknesses in Current Legislation

FDA's proposed amendments range from expanding FDCA notification requirements to include notifying FDA of an increase in demand for drugs to obtaining authority to require firms to provide shortage notifications for FDA-designated foods during a declared public health emergency.

These proposals, among many others, aim to support FDA's stated mission of protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. This alert is part one of a two-part alert series. When the FY 2025 budget is released, K&L Gates' Health Care and FDA team will publish part two of this alert discussing FDA's updated priorities as outlined in FDA's FY 2025 budget.

FOOTNOTES

[1] Skinny labeling is an exception to the FDA requirement that generic labeling be identical to the brand-name drug's labeling as the generic manufacturer must “carve out”—or exclude—from the labeling, diseases or patient populations that remain protected by use patents.

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