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Client Alert

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FDA Completes First Phase of "Transparency Initiative"

Last spring FDA created an internal task force to develop recommendations for enhancing the transparency of FDA's operations and decision-making processes. In recent months, the task force sought public comment on how to improve transparency through a public docket, an online blog, and two public meetings. Hundreds of comments were received from the regulated industry, patients, health care professionals, and consumers. On January 12, 2010, FDA announced it has completed the initial phase of this "Transparency Initiative" by rolling out a new Web-based feature for the public that provides basic information on the key program areas regulated by the agency.

FDA's Transparency Task Force decided to break down its initiative into three phases: Phase One -- Provide consumer information on how FDA does its work (launched Jan. 12th); Phase Two -- Make accessible information not yet posted on FDA's Web site more accessible, useful, and understandable to the public while protecting confidential information; and Phase Three -- Make key information available to the regulated community, such as updates on application reviews.

The FDA Basics Web feature released on January 12th, click here, contains general information about the agency and its regulated products, offers short videos that explain agency activities, and posts conversations with FDA staff. Users can select information on the following programs: drugs; medical devices; vaccines, blood products and biologics; foods; dietary supplements; cosmetics; color additives; animal and veterinary;, radiation-emitting products; and tobacco products. The web site contains a series of questions and answers on basic issues, such as:

- What information is available about adverse events for medical products?
- How can I get information about clinical trials for certain medical conditions?
- What does it mean when the FDA "clears" or "approves" a medical device and how can I find out whether a particular device has been "cleared or approved"?
- How can I file a complaint about a FDA-regulated product?

Moreover, as part of the implementation of Phase I of the Transparency Initiative, each month, different Centers and Offices at FDA will host an online ses-

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sion where the public can ask questions to senior FDA officials about a specific topic or just listen in to learn more about FDA.

Topics that are scheduled to be featured in the coming months include:

- February: Access to Investigational Drugs
- March: The Inspection Process

Although this FDA Basic Web feature is geared more to consumers, it is a useful reference source for health-care professionals interested in quick answers to general questions about FDA regulation. Phases II and III of the Transparency will likely unveil mechanisms for the dissemination of more substantive and topical information about FDA activities and decision-making processes that will be useful to both the regulated community and health care professionals. No timetable for implementation of these additional phases has been announced.