Confidence assets, the Consent Agreement provides for the Commission to appoint a trustee to divest the assets. Second, Disc-O-Tech is required to provide transitional services to the Commission-approved buyer. These transitional services, which are similar in form to what Disc-O-Tech would have provided to Kyphon, may be necessary for a smooth transition of the Confidence assets to the acquirer and to ensure continued and uninterrupted service to customers during the transition. The Consent Agreement also requires that Kyphon covenant not to sue the acquirer of the Confidence assets for infringing any intellectual property Kyphon acquired from Disc-O-Tech that is not being divested. This covenant covers not only the Confidence assets, but also extends to any developments an acquirer might make to the Confidence assets. This provision is designed as a safety net to ensure that Kyphon does not interfere with the acquirer's freedom to compete in the U.S. MIVCF treatment product market with a patent infringement lawsuit based on former Disc-O-Tech intellectual property. Finally, to ensure that the Commission will have an opportunity to review any attempt by Kyphon to acquire or license any of the Confidence assets at any time within the next two years, the proposed Consent Agreement contains a prior notice provision committing Kyphon to an H-S-R framework, even if such a transaction otherwise would be non-reportable.

The Order to Hold Separate and Maintain Assets that is included in the Consent Agreement requires that Disc-O-Tech maintain the viability of the Confidence business as a competitive operation until the business is transferred to a Commission-approved buyer. Specifically, Disc-O-Tech must maintain the confidentiality of sensitive business information, and take all actions required to prevent the destruction or wasting of the Confidence assets. Kyphon may not interfere with the Confidence business during the pendency of the divestiture by having any involvement in the Confidence business, making offers of employment to Disc-O-Tech employees involved in the Confidence business before the Confidence assets are divested, or interfering with Disc-O-Tech's suppliers of materials for the Confidence product.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or to modify its terms in any way.

By direction of the Commission, with Commissioners Harbour and Kovacic recused.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas to the agency by December 17, 2007.

ADDRESSES: Submit written proposed agendas regarding the Site Tours Program to Beth Duvall-Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6466, Silver Spring, MD 20993–0002. You can also reach Beth Duvall-Miller by telephone at 301–796–0700 or by e-mail at *elizabeth.duvallmiller@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to enhance significantly review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Firms interested in offering a site tour or learning more about this training opportunity should respond by (see **DATES**) by submitting a proposed agenda to Beth Duvall-Miller (see **ADDRESSES**).

Dated: October 9, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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