



U.S. Food and Drug Administration



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 3, 2004

BY FACSIMILE

Alan L. Beller
Director
Division of Corporation Finance
United States Securities and Exchange Commission
450 Fifth Street, N.W.
Washington, DC 20549

Stephen M. Cutler
Director
Division of Enforcement
United States Securities and Exchange Commission
450 Fifth Street, N.W.
Washington, DC 20549

Dear Messrs. Beller and Cutler:

This letter concerns support by the Food and Drug Administration (FDA) for activities undertaken by the Securities and Exchange Commission (SEC or Commission) and its staff. To improve the efficiency of our interactions, we propose the following:

Centralized Procedure for Referrals from FDA to SEC. FDA proposes to establish a single, centralized procedure for referring to the SEC instances in which FDA staff believe that an FDA-regulated firm has disseminated false or misleading statements to the investment community about the status of FDA review or other matters within FDA's regulatory authority. Under this procedure, the Food and Drug Division of the Office of the General Counsel of the Department of Health and Human Services would serve as the conduit for such referrals. We propose that the Deputy Director of the Division of Enforcement be designated as the person responsible for receiving the referrals on behalf of the SEC.

FDA Contacts. FDA proposes to identify an individual in each of FDA's main organizational components (known as Centers and the Office of Regulatory Affairs) to serve as points of contact for the SEC and its staff to use in requesting information (including, particularly, non-public information) from FDA. These

individuals would be responsible for assuring that such requests are handled promptly and thoroughly.

We also propose to designate the Associate Commissioner for Regulatory Affairs as the FDA liaison officer to work with the SEC in general areas of mutual interest. The liaison officer would be responsible for implementing this letter, and for assuring that SEC staff is notified of any personnel or organizational changes affecting the FDA contacts.

Training. FDA proposes to work with the SEC and its staff to identify opportunities for our two agencies to engage in training in areas of mutual interest. Such training could address, for example, the procedures used by FDA to respond to requests for non-public information or testimony.

Electronic Communication. FDA proposes to use electronic media whenever practicable in providing information or technical support to the SEC or its staff. FDA welcomes communications, including requests from the SEC for non-public information or testimony, by e-mail. We propose to use electronic media to the extent practicable when SEC staff request FDA review of statements in annual reports and other SEC filings made by FDA-regulated firms.

Non-Public Records/Information. We propose to continue sharing non-public information with the SEC consistent with our current practice, with one exception: instead of providing written authorization to individual FDA employees to share non-public information with the SEC or its staff on a case-by-case basis, we are providing "blanket" authorization to the FDA employees identified as SEC contacts to enable them to share information in response to all requests received from the SEC or its staff during a two-year period. We also intend to work on identifying additional steps to expedite that process, including seeking to reduce the associated paperwork.

FDA is committed to supporting the activities of the SEC and its staff as efficiently as possible within the bounds of our legal authority. If you have any questions, please contact David Elder, Director, Office of Enforcement at 301-827-0421.

Sincerely yours,

/s/

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

Attachments

cc: Giovanni P. Prezioso, Esq.
General Counsel
United States Securities and Exchange Commission
450 Fifth Street, NW
Washington, DC 20549