



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

February 4, 2004

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs
Department of Health & Human Services
Food and Drug Administration
Rockville, MD 20857

Dear Mr. Taylor:

This letter responds to your letter concerning support by the Food and Drug Administration (FDA) for activities undertaken by the Securities and Exchange Commission (SEC or Commission). We appreciate your effort both to acknowledge and strengthen the ongoing cooperation and coordination between the SEC and the FDA.

Centralized Procedure for Referrals from FDA to SEC. You proposed 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. We support this effort, and, as you suggest, we are designating the Deputy Director of the SEC Division of Enforcement as the person responsible for receiving the referrals on behalf of the SEC.

FDA Contacts. You proposed 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 believe this step will greatly assist our staff in working with the FDA in an efficient and effective manner.

Training. You proposed to work with the SEC and its staff to identify opportunities for our two agencies to engage in training in areas of mutual interest. We believe this is a constructive way of facilitating cooperation between and enhancing mutual understanding of our agencies.

Electronic Communication. You proposed to use electronic media whenever practicable in providing information or technical support to the SEC or its staff. We agree that use of electronic communication will expedite our work together.

Mr. John M. Taylor, III
Associate Commissioner for Regulatory Affairs
Page 2

Non-Public Records/Information. You proposed to continue sharing non-public information with the SEC consistent with your current practice and to endeavor to take steps to further expedite the process. We look forward to working with you to achieve this goal.

We appreciate FDA's strong interest in continuing to coordinate our agencies' activities in a cooperative manner. We welcome any further suggestions you may have on how to enhance this already-productive relationship. Please feel free to contact us if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen M. Cutler", followed by a horizontal line.

Stephen M. Cutler
Director
Division of Enforcement

A handwritten signature in black ink, appearing to read "Alan L. Beller", followed by a horizontal line.

Alan L. Beller
Director
Division of Corporation Finance