CELLTECH

June 29, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 99N-1852: Draft Guidance for Industry: "Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997"

Dear Sir or Madam:

This letter is in reference to the draft guidance cited above and the Notice published in the *Federal Register* on April 4, 2001 announcing the availability of the draft guidance and inviting comments for consideration in preparation of the final document.

Celltech Pharmaceuticals, Inc., is the holder of a number of new drug applications (NDAs) and abbreviated new drug applications (ANDAs). We are therefore directly impacted by the requirements of section 506B of the Federal Food, Drug, and Cosmetic Act regarding reports of postmarketing studies and the corresponding final rule published in the *Federal Register* on October 30, 2000 which made several changes to existing regulations. The subject draft guidance is intended to complement the final rule. Following are several comments Celltech has on the draft guidance.

1) The draft guidance seems to imply that FDA is requiring companies to submit a status report of any Chemistry, Manufacturing and Controls (CMC) study (e.g., stability study) whether the study is due to a formal commitment between FDA and the company or conducted voluntarily. This has implications that any development studies done on a marketed product, for example, to evaluate a new container/closure system or change in formulation, would need to be reported. This comment is based on the wording in the following sections of the draft guidance:

- (Page 2) Section II. Background, A. Reasons for Conducting and Types of Postmarketing Studies: "Postmarketing studies are those performed by you, a drug or biologics applicant, after FDA has granted approval to market its product...Postmarketing studies are also used to evaluate chemistry, manufacturing, and control (CMC) issues,...Generally, you would undertake a postmarketing study under one of the following three circumstances...3. A postmarketing study might be conducted on your own initiative without any request or requirement by FDA. Applicants conduct postmarketing studies on their own initiative for a variety of reasons, including the evaluation of a new indication or a new delivery system for a drug."

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- (Page 5) Section II. Background, B. Summary of the Final Rule that Implements Section 506B, 2. Specific Provisions, a. Human Drug Products, third bulletpoint: "Under new 21 CFR 314.81(b)(2)(viii), you must provide FDA with status reports on all other postmarketing studies being performed by you or on your behalf. The rule clarifies that you are required to include results from any CMC studies, which you have agreed to conduct, and from all ongoing stability studies." The accompanying flowchart in the draft guidance depicts that the status of studies undertaken voluntarily should be reported.

Celltech is concerned that FDA is hereby indicating that they would expect any CMC studies that a company undertakes voluntarily with a marketed product to be reported to them in the Annual Report, even if the studies are undertaken for developmental purposes to investigate possible future changes to a marketed product. Such developmental initiatives may never be pursued by the company. Thus, the need to include status reports on these studies in the Annual Report is outside the intent of Section 506B of the Act, would be of no value and a source of possible confusion to the Agency, and add an additional administrative burden to application holders. Therefore, please clarify FDA expectations in regards to the need to provide status reports of developmental CMC studies undertaken voluntarily by a company.

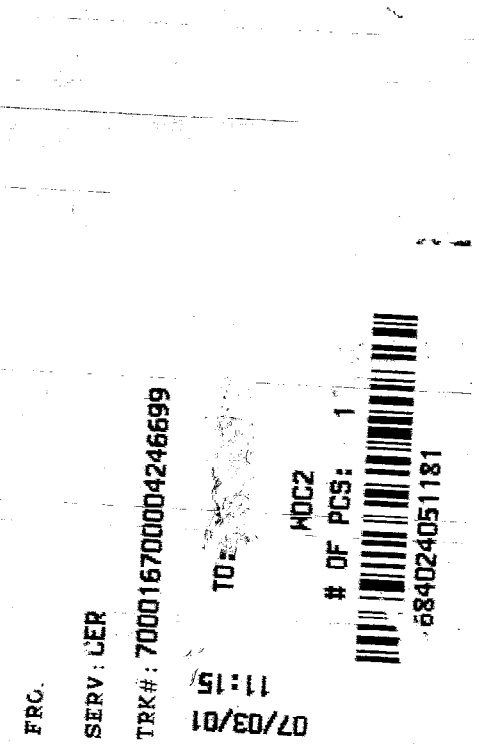
2) In Subsection D. How Should Applicants Submit their Postmarketing Study Status Reports?, 1. *Human Drug Products* (Page 11), it is not clear whether FDA is asking for a separate Form FDA 2252 be provided in the segregated section where the status reports are provided in addition to the Form FDA 2252 that is typically provided in the front of the Annual Report.

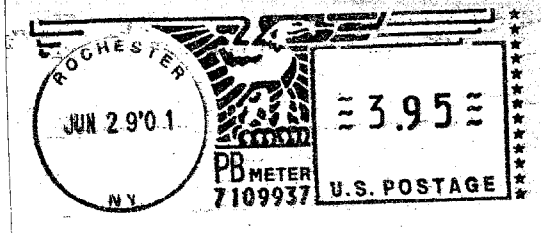
3) In Section IV. Content and Format of a Postmarketing Study Commitment Status Report (Page 13), it is not specified in this section whether the format of status reports on commitments/studies to be submitted under 21 CFR 314.81(b)(2)(viii) - e.g., CMC commitments/studies - should follow the same format as those reported under 21 CFR 314.81(b)(2)(vii).

If there are any questions regarding the above comments, please contact either the undersigned or Norma J. Cappetti, Director, Regulatory Affairs.

Sincerely,

Donald J. Handley, M.Sc., M.B.A.
Manager, Regulatory Affairs





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