**Medication Delivery**
**Regulatory Affairs**

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June 24, 2003

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

**RE: Federal Register Notice February 25, 2003**
**(Draft Guidance for Industry on Comparability Protocols-Chemistry, Manufacturing, and Controls Information; Availability/ FR Vol. 68, No.37, Pages 8772-8773)**

**Docket No. 03D-0061**

Dear Colleagues:

Baxter Healthcare Corporation is submitting the following comments on the draft guidance for "*Comparability Protocols-Chemistry, Manufacturing, and Controls Information*" published in February 2003.

Comment 1
Please clarify how a bundled submission approach may be used for comparability protocols associated with changes affecting multiple regulatory files? (line 95)

Comment 2
The draft guidance stated that if the study results do not meet the criteria specified in the approved comparability protocol then the applicant can decide not to pursue the change, or to submit a prior approval supplement. However, in cases where the deviated criteria have minimal potential to impact the product, we recommend using the reporting category that would normally apply for the type of change instead of being required to submit a prior approval supplement. (line 278)

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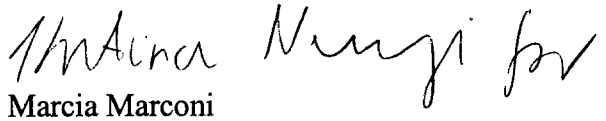
Comment 3
Per the draft guidance, modifications to approved protocols should be submitted as Prior Approval Supplements. In order to further reduce regulatory burden and streamline the submission review process, we recommend that the Agency consider using the reporting mechanism outlined in the "Changes to an Approved NDA or ANDA" guidance document for modifications to approved protocols. (line 298)

Comment 4
Please clarify the intent of Lines 426-436 (revision of a drug product or drug substance specification). The statement is: "If the recommended reporting category for the specification change is the same or lower than the designated reporting category for changes made under the comparability protocol, the specification can be updated and provided when a post approval CMC change implemented using the approved comparability protocol is reported to FDA."

Comment 5
Please clarify the need to provide a copy of the DMF authorization letter from the DMF holder when the regulatory file is reviewed for a change contained in a DMF (e.g. container resin change). We believe that a new DMF authorization letter is unnecessary if the FDA has received a DMF Letter of Authorization at the time of original filing of the application. (line 611)

Baxter appreciates the opportunity to comment on this important initiative. If you have any questions regarding our comments please don't hesitate to call Stacey Thompson at 847-270-5829 or Krisztina Nemenyi, Ph.D. at (847) 270-5268 or myself.

Sincerely,



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