Centocor

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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RE: Docket No. 03D-0061; Draft Guidance for Industry on Comparability Protocols – Chemistry, Manufacturing and Controls Information; Availability Federal Register, Tuesday, February 25, 2003

Dear Sir/Madam:

The draft guidance, according to the notice issued at the time of publication is intended to provide guidance for industry on preparing and using comparability protocols for post approval changes in chemistry, manufacturing and controls (CMC).

Detailed specific comments on the draft guidance are attached.

We appreciate the opportunity to provide comments on this guidance and are committed to collaborating with the Agency to develop improved versions of the guidance.

Sincerely,

Thomas M. Hogan
Senior Director
Worldwide Regulatory Affairs

Attachment

03D-0061 C4

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Centocor Comments on:
Draft FDA Guidance "Comparability Protocols – Chemistry, Manufacturing and Controls Information (Docket No. 03D-0061)
Table of Specific Comments
June 2003

Section	Guidance Line	Comment	Rationale
II. Background	41	Please clarify the definition of equivalence.	The term equivalence should be further defined as provided in the FDA Guidance for Industry "Changes to an Approved NDA or ANDA", Section IV.B.
II. Background	94	Safety or effectiveness	For consistency throughout document.
III. Planning a Comparability Protocol	150-151	Please provide examples of "cases" which would allow reduction of more than one reporting category.	To clarify the Agency's expectations and guidance in this area.
IV. Procedures for Comparability Protocols	271	Safety or effectiveness	For consistency throughout document.
IV. Procedures for Comparability Protocols	288-290	The requirement for a prior approval supplement (PAS) for a *revised* protocol is restrictive and should be reconsidered.	Depending on the modification to the protocol, a CBE or CBE-30 may be an appropriate mechanism for submission of a revised protocol. For example, if the protocol incorporates a change in an analytical method procedure that provides the same or increased assurance of the identity, strength, quality, purity or potency of the material being tested, perhaps submission of a revised protocol via a CBE or CBE-30 is appropriate.