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October 15, 2004

Division of Dockets management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

**Re: Comments to Docket No. 2004N-0267
Applications for Approval to Market a New Drug; Complete Response Letter;
Amendments to Unapproved Applications**

Dear Sir/Madam:

Celgene Corporation submits herein comments to the proposed rule published in the Federal Register on July 20, 2004 under Docket No. 2004N-0267.

Comment 1:

It appears under the proposed rule that a complete response letter or approval letter will be issued to the sponsor to indicate that the review cycle is complete. Can the Agency please provide comment and clarification as to what mechanisms of communication will be used during the review cycle to convey to sponsors potential deficiencies discovered during the Agency's review to enable sponsors to address such deficiencies as quickly as possible. It seems apparent that there would be very few applications, if any, that would completely satisfy FDA reviewers upon first review cycle.

Comment 2:

The third option for the recipient of a complete response letter, stated in proposed §314.110(b)(3), is to ask FDA to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the application or abbreviated application under section 505(d) or (j)(4) of the act, respectively. We would ask the FDA to consider having an independent evaluator within the Agency attend such hearings to confirm or negate grounds for denying approval. We would also like the FDA to comment on whether such hearings would be open public hearings.

Comment 3:

How does the Agency intend to ensure consistency across all review divisions regarding classification of resubmissions?

Comment 4:

Can the FDA please provide comment on the future of the Pre-Approval Inspection Program and how it would be incorporated into the proposed new review scheme.

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Comment 5:

We agree that it would be appropriate for the FDA to disclose to the public the existence of an NDA or ANDA following issuance of a complete response letter unless the applicant notifies the Agency by a specified date that the applicant had not publicly disclosed or acknowledged the existence of the application.

Comment 6:

We would encourage the FDA to consider an approval process whereby once the approval letter is issued to the applicant, the applicant may begin marketing of the product approved upon notification of approval and not have to address any additional regulatory hurdles prior to marketing of drug product, other than perhaps waiting for an exclusivity period to end of a previously approved drug that was granted such exclusivity.

Comment 7:

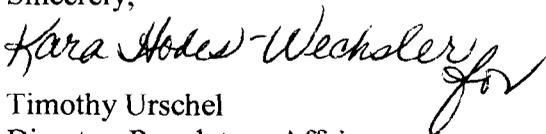
Under proposed §314.110(4)(iii) it states that a resubmission of an NDA supplement other than an efficacy supplement constitutes an agreement by the applicant to start a new 6-month review cycle beginning on the date the FDA receives the resubmission. It seems unreasonable that a resubmission e.g. – CMC or labeling supplements not requiring clinical data would require an additional six months for review.

Comment 8:

Under proposed §314.110 (4) the statement “Where appropriate, a complete response letter will describe the actions necessary to place the application or abbreviated application in condition for approval” the words “where appropriate” should be removed. The complete response letter should describe the actions and specify the data, as appropriate, to place the application or abbreviated application in condition for approval.

If you require further clarification or have any questions, please contact me.

Sincerely,



Timothy Urschel
Director, Regulatory Affairs
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