DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 22 2006

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Everett Carmody
President
SPEC Pharma
2329 Westlake Drive, Suite 5
Austin, Texas 78746

Re: Docket No. 2006P-0047/CP1

Dear Mr. Carmody:

This letter responds to your citizen petition dated January 20, 2006 (Petition). You request that the Food and Drug Administration (FDA) refrain from approving any abbreviated new drug application (ANDA) for Celestone Soluspan injection (betamethasone sodium phosphate and betamethasone acetate injection) unless and until the ANDA applicant demonstrates bioequivalence to the reference listed drug (RLD) product. FDA has considered the information submitted in your petition and addresses your request in this response. For the reasons explained below, your petition is granted.

I. BACKGROUND

On January 12, 2006, FDA published a notice in the *Federal Register* (71 FR 2047) announcing the Agency's determination that Celestone Soluspan injection (betamethasone sodium phosphate and betamethasone acetate injection) was not withdrawn from sale for reasons of safety or effectiveness, allowing FDA to approve ANDAs for Celestone Soluspan injection if all other legal and regulatory requirements are met. In the notice, FDA advises future ANDA applicants for Celestone Soluspan injection of the following:

- The RLD product may not be commercially available because, under a consent decree between FDA and the manufacturer, it is being made available in certain instances of medical necessity only.

- The reasons for the unavailability of the RLD product are not safety or effectiveness considerations associated with the drug product in general, but specific to the manufacturer.

- A future ANDA applicant who is unable to obtain the RLD product must contact the Office of Generic Drugs (OGD) for a determination of what showing is necessary to satisfy the requirements of section 505(j)(2)(A)(iv) of the Federal Food, Drug, and Cosmetic Act (the act).

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- If an ANDA is approved without a showing of bioequivalence to the RLD, the approved product will not be granted an AB rating in FDA's publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

In the notice, FDA advises future ANDA applicants that if the RLD product becomes commercially available prior to ANDA approval, the ANDA applicant will need to show bioequivalence to the RLD product.

In your petition, you state that the manufacturer, Schering-Plough Corporation (Schering-Plough), issued a press release on January 3, 2006, announcing completion of their CGMP Workplan and Validation Certification Program under the FDA consent decree. You also state that you contacted Schering-Plough as to the availability of the RLD product and were told by a representative that the restricted distribution of Celestone Soluspan injection had ended and increased quantities of the product will be available for distribution. Thus you request that FDA not approve an ANDA referencing Celestone Soluspan injection unless and until the applicant demonstrates bioequivalence to the RLD product.

II. DISCUSSION

Currently Celestone Soluspan injection is not being manufactured pursuant to a consent decree and is not subject to restricted distribution requirements. Schering-Plough has notified FDA that they have resumed normal distribution of Celestone Soluspan injection. As of April 6, 2006, Celestone Soluspan injection has been removed from FDA's drug shortage list.

Therefore, as described in the January 2006 notice, we currently expect ANDA applicants to show bioequivalence to the RLD product as described in section 505(j)(2)(A)(iv) of the Act.

III. CONCLUSION

Normal distribution of Celestone Soluspan injection has resumed and it is no longer on FDA's drug shortage list. Future ANDA applicants for Celestone Soluspan injection must show bioequivalence to the RLD product. Therefore, for the reasons discussed above, your petition is granted.

Sincerely,

Steven K. Galson, M.D., M.P.H.
Director
Center for Drug Evaluation and Research