



Food and Drug Administration
Rockville MD 20857

Cristina Neves, Regulatory Affairs Director
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Fervença
2705-906 TERRUGEM SNT PORTUGAL

0581 JAN 27 2006 14:42

Re: Docket Nos. 2004P-0406/CP1 and
2004P-0407/CP1

Dear Ms. Neves:

This formally responds to your two citizen petitions dated September 8, 2005, requesting that the Food and Drug Administration (FDA) determine whether Celestone (betamethasone sodium phosphate) injection equivalent to 3 milligrams (mg) base/milliliter (mL) (new drug application (NDA) 17-561) and Celestone Soluspan (betamethasone sodium phosphate plus betamethasone acetate) injection equivalent to 6 mg base/mL (NDA 14-602) were withdrawn from sale for reasons of safety or effectiveness.

The FDA has reviewed its records and has determined that Schering-Plough's (Schering's) betamethasone sodium phosphate injection and betamethasone sodium phosphate plus betamethasone acetate injection were not withdrawn from sale for reasons of safety or effectiveness. This determination allows FDA to maintain Schering-Plough's betamethasone sodium phosphate injection in the "Discontinued Drug Product List" of *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book).

Schering's betamethasone sodium phosphate plus betamethasone acetate injection may not be commercially available because, under a consent decree between FDA and Schering, it is being made available in certain instances of medical necessity only. The reasons for its unavailability are not safety or effectiveness considerations associated with the drug product in general, but specific to the manufacturer. The attached *Federal Register* notice contains specific information regarding abbreviated new drug applications (ANDAs) for betamethasone sodium phosphate plus betamethasone acetate injection.

Enclosed is a copy of the *Federal Register* notice announcing the FDA's determination. If you require any further information, please call me at 301-594-2041.

Sincerely yours,

Carol Drew
Office of Regulatory Policy (HFD-7)
Center for Drug Evaluation and Research

Enclosure

2004P-0406

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