



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

May 14, 2008

RE: ANDA 77-524

ADMINISTRATIVE RECONSIDERATION AND STAY OF ACTION

Pursuant to 21 CFR 10.33 (a) and (h), the Commissioner has concluded that FDA must reconsider the approval of Spear Pharmaceuticals Inc.'s (Spear) Abbreviated New Drug Application (ANDA) 77-524 for 5-fluorouracil. The Commissioner has concluded that it is in the public interest to do so because there are outstanding questions regarding this approval that the Agency must consider. To permit this reconsideration, Spear has agreed to a stay of the approval of ANDA 77-524 pursuant to 21 CFR 10.35(a) until May 30, 2008.

Accordingly, the approval of ANDA 77-524 is hereby stayed until May 30, 2008, when FDA anticipates that it will have completed its reconsideration of the application. Marketing, sales, and shipment under ANDA 77-524 are prohibited during the pendency of this administrative stay.

Jeffrey Shuren  
Associate Commissioner for  
Policy and Planning

EXHIBIT A

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May 14, 2008

Mr. Gary J. Buehler  
Director, Office of Generic Drugs  
Center for Drug Evaluation and Research  
U.S. Food & Drug Administration  
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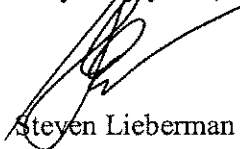
Re: Spear ANDA 77-524, Flurouracil Cream – Spear Pharmaceuticals

Dear Mr. Buehler:

Pursuant to our discussions earlier today with your colleagues at the FDA, Spear Pharmaceuticals, Inc. (“Spear”) hereby consents to an administrative stay of action through noon EDT on May 30, 2008 with respect to the above-referenced ANDA pursuant to 21 C.F.R. §§ 10.35(a) and 10.33(a) and (h). Spear hereby agrees that pursuant to the stay it will not market, sell or ship its Flurouracil cream, USP 5% product (the “ANDA Product”). Spear’s suspension of further sales, marketing and shipment of the ANDA Product will end at the earlier of:

- (a) noon (EDT) on May 30, 2008; or
- (b) dissolution of the administrative stay.

Very truly yours,



Steven Lieberman

SL:dob

cc: Gerald F. Masoudi, Esq.

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