SALUSPHARMA LLC

Division of Dockets Management
Food and Drug Administration
June 17, 2013
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OVERNIGHT COURIER 6/17/2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

Salus Pharma, LLC is submitting this Citizen Petition in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations of 21 CFR 314.161 to request that the Commissioner of the Food and Drug Administration determines whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determines whether Zefazone (cefmetazole sodium) injection, EQ 1gm base/vial and EQ 2 GM base/vial have been voluntarily withdrawn from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications in the *Approved Drug Products with therapeutic Equivalence Evaluations* ("The Orange Book"). Zefazone (cefmetazole sodium) injection, EQ 1 GM base/vial and EQ 2 GM base/vial, by Pharmacia and Upjohn were approved by the FDA on December 11, 1989 under NDA 50-637. Upon approval, Zefazone (cefmetazole sodium) injection, EQ 1 GM base/vial and EQ 2 GM base/vial were considered to be "listed drug products" by virtue of their listing in the Orange Book. The electronic Orange Book accessed on May 17, 2013, 33rd Edition, 2013 lists Zefazone (cefmetazole sodium) injection, EQ 1 GM base/vial and EQ 2 GM base/vial as discontinued products. According to the Federal Register dated 08/16/2001, Pharmacia Upjohn Co., informed FDA that Zefazone (cefmetazole sodium) injection, EQ 1 GM base/vial and EQ 2 GM base/vial is no longer marketed and has requested that FDA withdraw approval of the application. (Refer to Attachment 1).

Under FDA regulations, drugs are withdrawn from the market if the Agency withdraws or

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suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

Salus Pharma LLC acknowledges that there is currently no approved generic version of Zefazone (cefmetazole sodium) injection, EQ 1 GM base/vial and EQ 2 GM base/vial. Therefore, Salus Pharma LLC respectfully requests that the Food and Drug Administration makes the requisite determination as to whether Zefazone (cefmetazole sodium) injection, EQ 1 GM base/vial and EQ 2 GM base/vial were discontinued from sale for safety or efficacy reasons, in order to enable action on any ANDAs that refer to Zefazone (cefmetazole sodium) injection, EQ 1 GM base/vial and EQ 2 GM base/vial as the RLD.

C. **Environmental Impact**

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. **Economic Impact**

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. **Certification**

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which is unfavorable to the petition.

Respectfully submitted,

Nuo Wang, Ph.D.
Managing Member
(908) 723-1209

Attachment: The Federal Register dated August 8, 2001

cc: Martin Shimer (Office of Generic Drugs)

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2 Your Internal Billing Reference CITIZEN PETITION

3 To

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