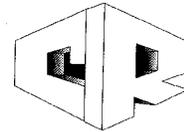


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Dockets Management Branch
HFA-305
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

August 7, 2007

CITIZEN PETITION

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This petition is submitted in quadruplicate pursuant to 12 CFR 10.30 and 21 CFR 314.161, and Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act to request the Commissioner of the Food and Drug Administration to declare that the drug product, Glucagon Hydrochloride (Glucagon), Eli Lilly, NDA Number 12-122, was withdrawn for reasons other than safety or effectiveness, as outlined below. If it has not been withdrawn for reasons of safety or effectiveness, then please state that it is suitable to submit an abbreviated new drug application (ANDA) for a generic of the drug.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Glucagon Hydrochloride for Injection is suitable for submission as an abbreviated new drug application (ANDA) and the reference listed drug (RLD) upon which this petition is based is, Glucagon, Eli Lilly, NDA 12-122 was voluntarily withdrawn from sale for reasons other than safety or effectiveness.

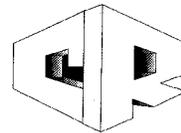
B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications (ANDAs). The List, referred to as the "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book), contains all FDA approved drug products. Glucagon, Glucagon Hydrochloride for Injection, (NDA 12-122) appears in the discontinued section of the Orange Book.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162).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)). Because the product appears in the discontinued section of the Orange Book (see Appendix 1), it is requested that the FDA determine whether the decision of Eli Lilly to discontinue marketing of Glucagon (glucagon hydrochloride for injection, NDA 12-122) was for reasons of safety or effectiveness.

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C. Environmental Impact

An environmental assessment report on the action requested in this petition is not required under 21 CFR 25.31(a).

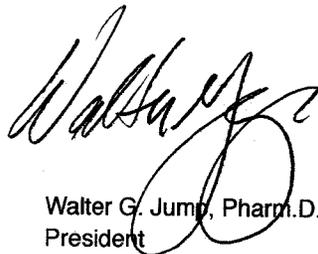
D. Economic Impact

This information will be provided upon request by the Agency, in accordance with 21 CFR 10.30 (p).

E. Certification

The undersigned certifies that to the best of its knowledge, 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.

Sincerely yours,



Walter G. Jump, Pharm.D.
President

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