

February 15, 2005

Division of Dockets Management
Food and Drug Administration
Dept. of Health and Human Services
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.



**Citizen Petition
Suitability Petition in Support of ANDA**

The undersigned submits this petition under 21 CFR 314.93 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to take administrative action.

A. Action requested

With regard to an Abbreviated New Drug Application, the petitioner seeks authorization to allow for a deviation in secondary package design from the Reference Listed Drug (Endrate®). Endrate® is packaged in trays of five glass ampoules per tray. McGuff Pharmaceuticals, Inc. petitions to provide a generic form of Endrate® (Edetate Disodium Injection, USP) in secondary package configurations of: a single box containing one vial and/or trays containing twenty-five vials per tray.

B. Statement of grounds

- 1) Existing Generic Equivalents:
 1. The proposed single box package configuration is used in other generic versions of the drug. Namely, those manufactured by Bioniche Pharma (ANDA #040437) and Steris Laboratories (ANDA #080391).
- 2) Response to Market
 - a. The twenty-five vial tray is a secondary package configuration which fulfills the requests for multiple vial tray packs called for by pharmacy/clinic customers using this drug. This configuration is similar to the RLD drug (Endrate®) five tray pack. Having two configurations allow us to better meet customer needs/requests.

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3) Functional Advantage:

- a. Current manufacturing operations are set-up to accommodate the requested secondary package configurations.

4) Unfavorable Information Statement:

To the best of our knowledge, there is no information regarding this configuration, known to the petitioner, which is unfavorable to the petitioner's position.

C. Environmental impact

The petitioner claims categorical exclusion from any requirement to prepare an environmental assessment (EA) or environmental impact statement (EIS). This claim is made under 21 CFR 25.31(a).

D. Economic impact

Available upon Commissioner's request.

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 are unfavorable to the petition.

A handwritten signature in black ink, appearing to read "Damon P. Jones", is written over a horizontal line.

Damon P. Jones
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