

May 17, 2001

**Mallinckrodt Inc.**

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**CITIZEN PETITION**

Mallinckrodt Inc. submits this petition pursuant to 21 C.F.R. §§ 10.20 and 10.30, under Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.93 to request the Commissioner of Food and Drugs make a determination that an Abbreviated New Drug Application may be submitted for Dextroamphetamine Sulfate Tablets, USP, 15 mg.

**A. Action Requested**

The petitioner requests that the Commissioner of the Food and Drug Administration make a determination that an Abbreviated New Drug Application may be submitted per 21 C.F.R. §314.122 for Dextroamphetamine Sulfate Tablets, USP (15 mg) for a product which relies on a listed drug that is no longer marketed.

**B. Statement of Grounds**

The Federal Food, Drug and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a new drug that differs in dosage strength from a listed drug provided the FDA has approved a petition that proposed the filing of such an application. This petition involves a change in the dosage strength for the proposed drug from that of the listed drug since any referenced listed drug of the same dosage strength is no longer being marketed. To the best of Mallinckrodt, Inc.'s knowledge, the discontinued product has not been withdrawn for reasons of safety or effectiveness.

The basis for this proposed Abbreviated New Drug Application is Dextroamphetamine Sulfate Tablets owned by Lannett (ANDA 85-652). However, this drug product is listed as "Discontinued" in the 21<sup>st</sup> edition of *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book). Furthermore, based on the Orange Book, there are no additional drug products of the same strength currently being marketed. A copy of the relevant pages of the Orange Book is included as Attachment 1.

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Mallinckrodt Inc. proposes to compare its Dextroamphetamine Sulfate Tablets, USP (15 mg) test product to Shire Richwood's DextroStat<sup>®</sup> (ANDA 84-051 Dextroamphetamine Sulfate Tablets, USP 10 mg). The reference product, Dextrostat, is classified AA in the 21<sup>st</sup> edition of Approved Drug Products with Therapeutic Equivalence Evaluations. Mallinckrodt Inc.'s proposed test product (Dextroamphetamine Sulfate Tablets, USP 15 mg), which differs only in inactives and strength, would also qualify for an AA rating. Therefore, with acceptable dissolution testing, there would be no need to conduct an *in-vivo* bioequivalence study.

The proposed strength that is the subject of this petition is clearly addressed in the approved labeling of the referenced drug product. DextroStat<sup>®</sup> recommended usual dosage for the treatment of narcolepsy is *5 mg to 60 mg per day in divided doses, depending on the individual patient response*. Furthermore, recommended usual dosages for Attention Deficit Disorder with Hyperactivity *start with 2.5 mg daily; daily dosage may be raised in increments of 2.5 mg at weekly intervals until optimal response is obtained. Only in rare cases will it be necessary to exceed a total of 40 mg per day.*

A copy of the reference listed drug labeling for DextroStat<sup>®</sup> (Attachment 2) and draft labeling for the proposed Dextroamphetamine Sulfate Tablets are enclosed (Attachment 3). The usage, indications and route of administration for the proposed product are the same as those for DextroStat<sup>®</sup>, the listed product.

### **C. Environmental Impact**

An environmental assessment on the action requested in this petition qualifies for a categorical exclusion under 21 C.F.R. 25.31. Therefore, an environmental assessment is not required for the requested action.

### **D. Economic Impact**

Pursuant to 21 C.F.R. 10.30 (b), economic impact information is to be submitted only when requested by the Commissioner. Mallinckrodt Inc. will promptly provide such information if so requested.

**E. Certification**

Mallinckrodt Inc. certifies that, to its best knowledge and belief, 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.

Respectfully submitted,



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