MYLAN PHARMACEUTICALS INC
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March 19, 2003

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

Citizen Petition

Dear Sir or Madam:

Mylan submits this petition, in quadruplicate, pursuant to 21 CFR 10.30 requesting the Commissioner of the Food and Drug Administration to amend the "Approved Drug Products with Therapeutic Equivalence Evaluation" list (the "Orange Book"), 23rd edition, as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration amend the "Orange Book" to designate Jones Pharma's Levoxyl® (levothyroxine sodium) Tablets (NDA #21-301) as an additional reference listed drug product.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications. That list, referred to as the "Orange Book", contains all FDA approved drug products. The FDA has decided through the comment and rule making process that it will designate all reference listed drug (RLD) products, and that the designated reference listed drug products will be the same drug products selected by the Agency as the reference standard for bioequivalence testing for a duplicate generic version of the RLD (57 FR 17950, 17954). FDA's intention in this regard was to designate a single reference listed drug against which all generic versions must be shown to be bioequivalent and thus avoid possible variations among generic drugs and their brand name counterparts (57 FR 17950, 17954). For multiple source NDA drug products or multiple source drug products without an NDA, the FDA has decided to generally designate the market leader as the reference-listed drug (57 FR 17950, 17958).

However, for multiple source drug products, a product **not** designated as the reference listed drug and **not** shown to be bioequivalent to the designated reference listed drug product selected by the agency, may be shielded from direct generic competition. In this specific case, the current Orange Book does designate Levoxyl® (levothyroxine sodium) Tablets as a reference listed drug product although it was not the first NDA approved for this ingredient. The FDA, when approving multiple NDAs for this specific drug product, had the foresight to recognize that ANDA applicants may seek to compete against various segments of the levothyroxine sodium market and because the NDAs approved were not rated as therapeutically equivalent, the agency, on its own initiative designated each levothyroxine sodium NDA as a RLD. Mylan applauds the agency for its actions however, we are concerned that in taking its initiative, the administrative requirement for an applicant to consult with the agency (57 FR 17950, 17954) may not have been met. Historically, a request to designate a second reference listed drug product has come in the form of a petition submitted under 21 CFR 10.30 seeking such a determination. Therefore to assure that all administrative procedures for such designation have been met, Mylan is formally seeking the agency's determination, that Levoxyl® (levothyroxine sodium) Tablets, NDA #21-301 be designated as an additional reference listed drug.

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Human Resources	(304) 598-5406	Medical Unit	(304) 598-5445	Research & Development	(304) 285-6409
		Product Development	(304) 285-6411	Sales & Marketing	(304) 598-3232

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31

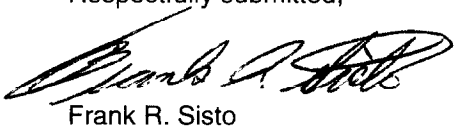
D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the Agency.

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 that are unfavorable to the petition.

Respectfully submitted,



Frank R. Sisto
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FRS/dn