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

SUITABILITY PETITION

Dear Sir or Madam:

Orgenus Pharma, Inc. hereby submits this Suitability Petition on behalf of Orchid Healthcare as its US Agent.

This petition is submitted, in quadruplicate, pursuant to 21 CFR § 10.20 and § 10.30, as provided for in 21 CFR § 314.93 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 Memantine Hydrochloride Orally Disintegrating Tablets 5 mg and 10 mg are suitable for submission as an abbreviated new drug application (ANDA).

Action Requested

The petitioner requests that the commissioner of the Food and Drug Administration declare that Memantine Hydrochloride Orally Disintegrating Tablets 5 mg and 10 mg are suitable for submission as an ANDA. The reference listed drug products (RLDs) upon which this petition is based are Namenda® Tablets 10 mg & 5 mg (NDA # 021487) and Oral Solution 2 mg / ml (NDA # 021627), manufactured by Forest Pharmaceuticals Inc. (See copy of the page from the current Electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, Attachment 1). The petitioner seeks a change in dosage form (from the approved dosage forms of tablets and solution to an orally disintegrating tablets) from that of the RLD products.

Statement of Grounds

The proposed drug product, Memantine Hydrochloride Orally Disintegrating Tablets, is presented for administration by placing on the tongue, which will disintegrate in a matter of seconds and swallowing the disintegrated tablet with or without water.

The Orally Disintegrating Tablets would be a viable alternative to both of the currently marketed dosage forms, Tablets and Oral Solution, due to the following advantages:

- Convenient for patients who have difficulty in swallowing tablet dosage form.
- Unit dose dispensing of drug (in comparison with solution form).
- Does not require a dosing device as in solution form.

2007P-0203

CPI

Orgenus Pharma, Inc.

(A Subsidiary of Orchid Pharmaceuticals, Inc.)
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- Ease of carrying (in comparison with a bulky solution container).
- Ease of administration. Administration with water is not required.

The proposed product will differ only in dosage form. The indications, strengths, route of administration, intended patient population and recommendations for use will remain the same as of the RLD products. The proposed product will be formulated so as to be bioequivalent to current tablet formulation (RLD), marketed by Forest Pharmaceuticals Inc. The proposed product will contain inactive ingredients that are generally recognized as safe (GRAS) and at levels previously approved by USFDA. Therefore there will be no difference between the safety and efficacy of the proposed product and RLD products.

The proposed product will be labeled in accordance with the approved labeling of RLD products upon which this petition is based. Any difference in labeling will relate only to the differences in dosage forms. The indications, warnings, dosage, route of administration and intended patient population will remain the same as that of RLD products.

Therefore the petitioner requests the commissioner to find that a change in dosage form from Tablets and Oral Solution to Orally Disintegrating Tablets should raise no questions of safety or effectiveness and the Agency should approve the petition.

Pediatric Use Information

The petitioner is aware that, according to the Pediatric Research Equity Act (PREA) of 2003, which amended the FDC Act, a pediatric assessment is required for a new proposed product with a new dosage form.

The petitioner hereby requests that a waiver from the conduct of pediatric studies under 21 U.S.C. § 355c(a)(4)(A) pursuant to 21 CFR § 314.55(c)(2)(i) be granted for the approval of this petition to permit a subsequent ANDA filing. The request for waiver is justified as the drug or biological product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients and is not likely to be used in substantial number of pediatric patients.

For the aforementioned reasons, the undersigned requests that the Commissioner grant this petition and authorize submission of an ANDA for Memantine Hydrochloride Orally Disintegrating Tablets 5 mg and 10 mg.

Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR § 25. 31.



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.

Certification

The undersigned certifies that to the best of his 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,

A handwritten signature in black ink, appearing to read "Satish Srinivasan", with a horizontal line extending to the right.

Satish Srinivasan
Director, Business Development & Operations

Attachments:

1. Approved Drug Products with Therapeutic Equivalence Evaluations
2. Draft labeling proposed for Memantine Hydrochloride Orally Disintegrating Tablets
3. Labeling for the RLD, Namenda ® Tablets / Oral Solution

Namenda ® is registered Trademark of Forest Pharmaceuticals Inc.