Strides

November 16, 2006

Division of Dockets Management
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:

This Citizen's Petition is submitted by Strides Inc., under the authority of 21 CFR §10.30, 21 CFR §314.93, and Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FDCA). The petitioner is requesting that the Food and Drug Administration permit the filing of an Abbreviated New Drug Application for a proposed drug product that has the same route of administration, the same dosage form, the same strength of one of the active ingredients in a combination drug, and is expected to have the same therapeutic effect as that of a reference product in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, but differs with respect to one of the active ingredients in a combination drug.

A. Action Requested

By this petition, the Commissioner of the Food and Drug Administration is being requested to declare that:

(1) A new drug application for Ibuprofen Potassium 200 mg Phenylephrine Hydrochloride 10 mg Capsules is suitable for submission as an Abbreviated New Drug Application (ANDA), pursuant to 21 CFR §314.94;

(2) The reference product on which the contents of this petition are based is Advil Cold and Sinus® (Ibuprofen Potassium 200 mg Pseudoephedrine Hydrochloride 30 mg Capsules);

(3) Therefore, a request is being made to substitute a different active ingredient for one of the active ingredients in a listed combination drug.

At this time, the undersigned is also requesting a waiver of the requirement to conduct pediatric studies in accordance with 21 CFR §314.55(c)(2). The basis for this request is discussed in Section C below.

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B. Statement of Grounds

Section 505(j)(2)(C) of the FDCA allows for the submission of an Abbreviated New Drug Application for a proposed new drug product in which one active ingredient is substituted for one of the active ingredients in the Reference Listed Drug on which it is based, provided that the Commissioner of Food and Drugs has approved a petition, filed by or on behalf of the applicant, requesting a declaration that an application to market a drug product with such change is suitable for an ANDA submission.

The over-the-counter monograph for oral nasal decongestants includes both pseudoephedrine hydrochloride and phenylephrine hydrochloride (please refer to 21 CFR 341.20(a)). Therefore, phenylephrine hydrochloride and pseudoephedrine hydrochloride are equally safe and effective when used within the dosage limits and in the dosage forms established for each ingredient, and no investigations must be conducted to show the safety and effectiveness of the proposed drug product. Unlike pseudoephedrine hydrochloride, however, phenylephrine hydrochloride is not a chemical precursor used in the illicit manufacture of methamphetamine and methcathinone. The substitution of phenylephrine hydrochloride for pseudoephedrine hydrochloride in the proposed drug product therefore is advantageous to the public health.

In support of this petition, the following information is being provided:

(1) The proposed drug product is a soft gelatin capsule with the same route of administration, the same dosage form, and the same strength of one of the active ingredients in the combination reference product, Advil Cold and Sinus® Capsules. A copy of the most recent Orange Book listing of "Approved Drug Products with Therapeutic Equivalence Evaluations" is provided (Attachment 1).

(2) The proposed drug product will be labeled with the same conditions of use as the reference product, and is expected to have the same therapeutic effect when used as indicated in the labeling. Labeling for the proposed drug product and the reference product will differ with respect to the substituted active ingredient (phenylephrine for pseudoephedrine), the manufacturer identification and the contact information, and may differ with respect to the inactive ingredients. A draft of the proposed drug product labeling is provided (Attachment 2). A copy of the current reference product labeling also is provided (Attachment 3).

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C. Pediatric Waiver Request

In December of 2003, Congress passed the Pediatric Research Equity Act of 2003 (the PREA) that amended the FDCA to provide the Agency authority to require drug firms to study drugs in pediatric patients, if the Agency concludes that such study would provide beneficial health data for that patient population. The PREA specifically requires that a request for a new active ingredient in a combination product is subject to pediatric evaluation. The PREA also provides for a waiver from such requirement if the drug:

1. Does not represent a meaningful therapeutic benefit over existing therapies; and
2. Is not likely to be used in a substantial number of pediatric patients.

The petitioner hereby requests that a waiver from the conduct of pediatric studies be granted for the approval of this petition to permit an ANDA filing.

The marketing rationale for the proposed drug product is related to thwarting the illicit manufacture of methamphetamine and methcathinone, not to any purported therapeutic superiority of phenylephrine hydrochloride as compared to pseudoephedrine hydrochloride. As mentioned above, both active ingredients are included in the over-the-counter monograph for oral nasal decongestants (please refer to 21 CFR 341.20(a).

Furthermore, the drug is not likely to be used in a substantial number of pediatric patients because numerous already-marketed drug products that combine ibuprofen with a nasal decongestant active ingredient are labeled for pediatric use, whereas the RLD labeling and proposed drug labeling state: "children under 12 years of age: consult a doctor." In addition, neither ibuprofen nor phenylephrine hydrochloride is included in the most recent List of Drugs for Which Pediatric Studies Are Needed (Attachment 4).

D. Environmental Impact

The applicant claims a categorical exclusion under 21 CFR §25.31.

E. Economic Impact

Information will be provided upon request of the Commissioner.

F. 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 be unfavorable to the petition.

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Respectfully submitted by:

N Gaddipati

Nehru Gaddipati, PhD, RPh
President, R&D

Strides Inc.
37 Veronica Avenue
Somerset, New Jersey 08873

Telephone: (732) 828-5500 x 1601
Direct Line: (732) 839-1601
Facsimile: (732) 249-0225
Email: nehru@stridesusa.com

Enclosures: Attachments 1, 2, 3 and 4