the WOOD BURDITT group

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

Re: EasiSlush® Sodium Chloride Solution for Sterile Slush Preparation, 0.9% Sodium Chloride Irrigation, USP (ANDA Preassigned # 216849)

SUITABILITY PETITION

Dear Sir/Madam:

The Wood Burditt Group, the U.S. Agent for its client, Bridge to Life ("BTL") submits this petition, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR §10.30, requesting the Commissioner of the Food and Drug Administration (FDA) to provide a determination that 0.9% Sodium Chloride Irrigation USP, with a 1250 mL (1.25 L) fill volume in a 2L flexible plastic container (change in strength), is suitable for submission in an Abbreviated New Drug Application (ANDA).

A. Background

BTL filed Controlled Correspondence 00094773 (Attachment 1) with two requests:

1. If it is acceptable to use a different primary container material than that used by the RLD?
2. If the drug product fill volume of 1.25 L, the primary container total fill volume capacity of 2 L and the resulting head space of the primary container meet the ANDA requirements for the definition of "sameness" with the RLD?

FDA responded affirmatively to the first question. But on the second request, it concluded that an affirmative answer would require submission of a Suitability Petition. (See FDA Response to CC 00094773 – Attachment 2) This petition follows that advice.

B. Action Requested

BTL requests that the Commissioner of the FDA determine that 0.9% Sodium Chloride Irrigation USP with a 1,250 mL (1.25 L) fill volume in a single dose 2L flexible plastic container is suitable for submission in an ANDA. The Reference Listed Drug (RLD) upon which this petition is based is 0.9% Sodium Chloride Irrigation, USP with a 1,000 mL fill volume. The RLD is a solution for slush for irrigation (NDA 019319, held by Baxter

Healthcare Corp). Therefore, BTL is seeking a change in fill volume (strength) (total drug per container) and in container size.

C. Statement of Grounds

FD&C Act § 505(j)(2)(A) permits the submission of an ANDA for a drug product that differs in dosage strength from that of the listed drug provided the FDA has approved a petition submitted pursuant to FD&C Act§ 505(j)(2)(C).

The RLD is .09% Sodium Chloride Irrigation, USP, in a 1,000 mL flexible plastic container. A copy is attached of a) the listing in the current electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (Attachment 3) and the b) the current RLD labeling (Attachment 4). BTL's proposed ANDA drug is also .09% Sodium Chloride Irrigation, USP, but the proposed fill volume of the drug product is 1,250 mL in a single dose 2L flexible container; it, therefore, represents a change in strength (total drug fill content) and packaging size.

Pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, the abbreviated new drug application (ANDA) for a proposed drug product is not obligated to use the same container closure system as the one used by the applicant of the reference-listed drug. However, the ANDA is required to provide appropriate information to ensure that the proposed drug product has the same conditions of use and the same labeling as the RLD pursuant to Section 505(j)(2)(A)(v) of the FD&C Act.

0.9% Sodium Chloride Irrigation, USP is a sterile, non-pyrogenic, isotonic, clear, colorless, solution intended for the preparation of iced slushed solution. Iced slushed solution is used to create regional hypothermia in order to reduce and minimize manifestations of warm-temperature ischemia during open body cavity surgical procedures.

The changes proposed by BTL in fill volume (strength) and container size do not affect dosing, administration or conditions of use. The indications, warnings and directions for use will remain the same as that of the RLD. According to the Dosage and Administration section of the RLD's labeling, "The volume of slushed solution required will vary with patient's age, clinical condition, cooling effect desired and duration of cooling effect desired, according to physician's instructions." Thus, the proposed 1,250 mL fill volume will provide an appropriate presentation when the drug product is required in different clinical settings.

BTL's draft labeling for the proposed product is included in Attachment 5. A side-by-side comparison of the RLD (left column) and the ANDA product (right column) is also attached as Attachment 6. No change from the RLD is proposed in labeling for the 1,250 mL fill size, with the exception of the obvious changes in fill volume (strength) sought in this petition, administrative information and container closure size.

Therefore, the petitioner's request for the Commissioner to find that a change in fill volume (strength) i.e., a change in total drug content to include 1,250 mL in flexible plastic containers should raise no questions of safety or effectiveness, and the Agency should approve the petition.

D. Environmental Impact

In Accordance with the requirements set forth in 21 CFR 25.31, the petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment.

E. Economic Impact

Pursuant to 21 CFR 10.30(b) an economic impact analysis will be provided upon request.

F. Certification

BTL certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and includes representative data and information known to the petitioner, which is unfavorable to the petition.

Should you have any questions, please feel free to contact the undersigned.

Respectfully submitted,

Richard O. Wood