DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 77-218

JAN 12 2005

Fleming & Company, Pharmaceuticals
Attention: Thomas S. Johnson
President
1733 Gilsinn Lane
Fenton, MO 63026

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated July 23, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for ThyroShield™ (Potassium Iodide Oral Solution USP), 65 mg/mL. This application was granted "Expedited Review" status by the Center for Drug Evaluation and Research (CDER) based upon the Center's determination that the drug product is a medical necessity which is not currently available within the United States.

Reference is also made to your amendments dated November 29, 2004; and January 3 and January 10, 2005. Reference is also made to the Suitability Petition (04P-0092/CP1) submitted under Section 505(j)(2)(C) of the Act and approved on March 3, 2004, permitting you to file this ANDA for a drug product that differs in dosage form from the reference listed drug product (RLD); i.e., from an oral tablet to an oral solution.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The drug product, ThyroShield™ (Potassium Iodide Oral Solution, USP), 65 mg/mL, can be expected to have the same therapeutic effect as an equivalent dose of the reference listed drug product (RLD) that the agency relied upon as the basis of safety and effectiveness.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

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Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research