DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

ANDA XXXXXX

GENERAL CORRESPONDENCE

Firm
Attention:
Address

Dear Sir/Madam:

Please refer to your Abbreviated New Drug Application (ANDA) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for [INSERT ACTIVE INGREDIENTS AND DOSAGES].

On January 14, 2011, the Food and Drug Administration (FDA) published a *Federal Register* notice informing holders of ANDAs for combination prescription products with acetaminophen strengths greater than 325 mg that FDA would initiate withdrawal proceedings for any such products that remained on the market 3 years after that date. The notice strongly encouraged these sponsors to submit requests for withdrawal of their products' approved applications under within this 3-year period.

According to our records, you currently market at least one fixed-combination prescription drug with an acetaminophen strength greater than 325 mg. To date, you have not requested withdrawal of your product(s) under § 314.150(d). Since the January 14, 2014, deadline is rapidly approaching, we encourage you to submit a request for withdrawal as soon as possible. After the deadline, FDA intends to use its authority under the FD&C Act to initiate withdrawal proceedings for your product(s).

When you submit a request for withdrawal, prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission:

REQUEST FOR WITHDRAWAL OF ANDA UNDER 21 CFR § 314.150(d)

If you have any questions, call Tina Nhu, Regulatory Project Manager, at (240) 276-8548.

We have enclosed the *Federal Register* notice for your reference.

Sincerely,

{See appended electronic signature page}

Wm Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Enclosures: Withdrawal Template
Federal Register Notice

ANDA XXXXXX

REQUEST FOR WITHDRAWAL OF
ANDA UNDER 21 CFR § 314.150(d)

Dr. Kathleen Uhl
Office of Generic Drugs, CDER
Document Control Room
7620 Standish Place
Rockville, MD 20855

Dear Madam:

Please refer to our abbreviated new drug application (ANDA) ######, submitted under the Federal Food, Drug and Cosmetic Act for [insert description of product(s)].

In a Federal Register notice issued on January 14, 2011, we were informed by the Food and Drug Administration (FDA) that acetaminophen prescription drugs containing more than 325 mg of acetaminophen per dosage unit (tablet or capsule) do not provide a sufficient margin of safety to protect the public against the serious risk of acetaminophen induced liver injury.

FDA therefore requested that ANDA holders of acetaminophen containing products greater than 325 mg permit the agency to withdraw approval of applications for these products.

Accordingly, we voluntarily request withdrawal of the above Referenced ANDA under 21 CFR 314.150(d), and waive any opportunity for a hearing otherwise provided under 21 CFR 314.150.

Sincerely,