DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 11459/S-048
NDA 11795/S-025

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Denise Tindle
Director, Worldwide Safety and Regulatory
235 East 42nd Street
New York, NY 10017

Dear Ms. Tindle:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received May 9, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vistaril (hydroxyzine pamoate) 25 mg and 50 mg capsules (NDA 11459), and Vistaril (hydroxyzine pamoate) 25mg/5 ml oral suspension (NDA 11795).

We also refer to our letter dated April 9, 2014 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Vistaril (hydroxyzine pamoate). This information pertains to the risk of association between the use of hydroxyzine and fixed drug eruptions.

These supplemental new drug applications provide for the following revisions to the labeling for hydroxyzine pamoate consistent with our April 9, 2014 letter:

The addition of the following new subsection under **ADVERSE REACTIONS:**

Skin and Appendages: Oral hydroxyzine hydrochloride is associated with fixed drug eruptions in post-marketing reports.

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the

addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, email Sharonjit Sagoo, Regulatory Project Manager, at Sharonjit.Sagoo@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Victor Crentsil, MD, MHS
Deputy Director for Safety
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VICTOR CRENTSIL
06/03/2014