



ANDA 071413/S-019

SUPPLEMENT APPROVAL

APP Pharmaceuticals, LLC
Attention: Kathleen Dungan
1501 East Woodfield Road
Suite 300E
Schaumburg, IL 60173

Dear Madam:

Please refer to your supplemental abbreviated new drug application (sANDA) dated September 22, 2010, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fluphenazine Decanoate Injection USP, 25 mg/mL.

We also refer to our letter dated August 24, 2010 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Fluphenazine Decanoate Injection, USP. This information pertains to the risk of extrapyramidal signs (EPS) and/or withdrawal symptoms in neonates, reported in association with use of conventional and atypical antipsychotics during pregnancy.

This supplemental new drug application provides for revisions to the labeling for Fluphenazine Decanoate Injection, USP consistent with our August 24, 2010 letter.

We have completed our review of this supplemental application. It is 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, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to, except with the revisions indicated, the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effectuated" (CBE) supplements. 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 via publicly available labeling repositories.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

Also within 14 days from the date of this letter, amend all pending supplemental applications for this ANDA, including pending CBE supplements, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes with the revisions approved in this supplemental application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this ANDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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

If you have any questions, call Carrie Lemley, Labeling Project Manager, at (240) 276-8986.

Sincerely,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling