

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

209905Orig1s000

Trade Name: Evekeo ODT orally disintegrating 5, 10, 15 and 20 mg tablets

Generic or Proper Name: Amphetamine sulfate

Sponsor: Arbor Pharmaceuticals, LLC

Approval Date: January 30, 2019

Indication: For the treatment of Attention Deficit Hyperactivity Disorder (ADHD)

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209905Orig1s000

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APPROVAL LETTER



NDA 209905

NDA APPROVAL

Arbor Pharmaceuticals, LLC
Attention: Tina Morton
Senior Manager, Regulatory Affairs
6 Concourse Parkway
Suite 1800
Atlanta, GA 30328

Dear Ms. Morton:

Please refer to your New Drug Application (NDA) dated and received March 30, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Evekeo ODT (amphetamine sulfate) orally disintegrating 5, 10, 15, and 20 mg tablets.

This new drug application provides for the use of Evekeo ODT (amphetamine sulfate) orally disintegrating tablets for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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 Prescribing Information and Medication Guide) 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 *SPL Standard for Content of Labeling Technical Qs and As*, available at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

We acknowledge your January 28, 2019, and January 29, 2019, submissions containing final printed carton and container labeling.

ADVISORY COMMITTEE

Your application for Evekeo ODT was not referred to an FDA advisory committee because this drug is not the first in its class.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

This product is appropriately labeled for use in ages 6 to 17 years for this indication. Therefore, no additional studies are needed in this pediatric group.

We are waiving the pediatric study requirement for ages less than 3 years there is evidence strongly suggesting that the drug product would be unsafe.

We are deferring the requirement for ages 3 to 5 years for this application until a smaller tablet strength is developed for this age group.

Your deferred pediatric requirement is required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act. The status of this postmarketing requirement must be reported annually according to 21 CFR 314.81 and section 505B.

PMR 3566-1	Development of a 2.5 mg strength OD tablet for use in 3 to 5 year olds, including formulation development, associated pharmaceutical testing, generation of adequate stability data, and collection of adequate data supporting a biowaiver for this strength*.
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Completion date/supplement submission date: March 1, 2021

*The NDA Supplemental-PMR should include a biowaiver request for the proposed 2.5 mg strength Evekeo oral disintegrating tablet (ODT), with the appropriate CFR citation and supporting information including evidence of (1) in vitro dissolution profiles similarity, when

compared to the bio-strength (20 mg) ODT that was shown to be bioequivalent to Evekeo tablets, as well as the lowest approved (5 mg) strength of the ODT, when using single tablets per vessel and the approved dissolution method for Evekeo ODT, (2) similar disintegration times, (3) formulation composition proportionality of the 2.5 mg strength ODT to the 20 mg ODT in terms of the type and quantities of the active and inactive ingredients, and (4) any information regarding dose proportionality/PK linearity covering the therapeutic or clinical dose range. Note that the adequacy of the biowaiver request will be determined during supplemental NDA review.

Response to this required pediatric postmarketing requirement must be submitted as a supplement to your approved NDA with the proposed labeling changes you believe are warranted. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the Prescribing Information, Medication Guide, and Patient Package Insert (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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, call Keith Kiedrow, Team Leader, Senior Regulatory Project Manager, at 301-796-1924.

Sincerely,

{See appended electronic signature page}

Tiffany Farchione, M.D.
Acting Division Director
Division of Psychiatry Products
Office of Drug Evaluation I

ENCLOSURE(S):

- Content of Labeling
- Prescribing Information
- Medication Guide
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TIFFANY R FARCHIONE
01/30/2019 05:07:11 PM