CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

210875Orig1s000

Trade Name:	Kynmobi sublingual film
Generic or Proper Name:	apomorphine
Sponsor:	Sunovion Pharmaceuticals, Inc.
Approval Date:	May 21, 2020
Indication:	For the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease.

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APPROVAL LETTER

NDA 210875

NDA APPROVAL

Sunovion Pharmaceuticals, Inc.
Attention: Sonya A Roeloffzen Stokowski
Director, Global Regulatory Affairs
84 Waterford Drive
Marlborough, MA 01752

Dear Ms. Roeloffzen Stokowski:

Please refer to your new drug application (NDA) dated March 29, 2018, received March 29, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Kynmobi (apomorphine) sublingual film.

We acknowledge receipt of your amendment dated November 21, 2019, which constituted a complete response to our January 29, 2019, action letter.

This new drug application provides for the use of Kynmobi (apomorphine) sublingual film for the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease.

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.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and Instructions for Use) 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.*[2]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

We acknowledge your May 18, 2020, submission containing the final printed carton and container labeling.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable. Parkinson's disease in the pediatric population is extremely rare.

POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o)(3) of the FDCA authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute.

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to identify an unexpected serious risk of drug-drug interactions caused by the norapomorphine glucuronide metabolite.

Furthermore, the active postmarket risk identification and analysis system as available under section 505(k)(3) of the FDCA will not be sufficient to assess this serious risk.

Therefore, based on appropriate scientific data, FDA has determined that you are required to conduct the following studies:

3861-1 Conduct in vitro studies to evaluate the drug-drug interaction potential of the norapomorphine glucuronide major metabolite from APL-130277 as a perpetrator for major CYP enzymes and transporters. Refer to the FDA guidance on in vitro drug interaction studies (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/vitro-drug-interaction-studies-cytochrome-p450-enzyme-and-transporter-mediated-drug-interactions).

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