NDA 019101/ 0 0

PPLEMENT APPROVAL

Hikma Pharma euti als U A In . c
2 Esterbrook Lane
Cherry Hill, NJ 08003 4099

Attention: Venkata ai Tankashala
Asso iate Dire tor, Regulatory Affairs

Dear Mr. Tankashala:

Please refer to your supplemental new drug appli ation (sNDA) dated and re eived eptember 20, 2022, and your amendments, submitted under se tion 505(b) of the Federal Food, Drug, and Cosmeti A t (FDCA) for Fentanyl itrate inje tion.

This Prior Approval upplement proposes to add 0.025 mg/0.5 mL and 0.05 mg/1 mL (0.05 mg/mL) pre filled syringe presentations to Fentanyl itrate inje tion approved labeling.

We have ompleted our review of this appli ation, as amended. It is approved, effe tive on the date of this letter, for use as re ommended in the en losed agreed upon labeling.

WAIVER OF ½ PAGE LENGTH REQ UREMENT FOR HIGHLIGHT

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Pres ribing Information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the ontent of labeling [21 CFR 314.50(l)] in stru tured produ t labeling (PL) format using the FDA automated drug registration and listing system (eLI T), as des ribed at FDA.gov.[1] Content of labeling must be identi al to the en losed labeling (text for the Pres ribing Information), with the addition of any labeling hanges in pending "Changes Being Effe ted" (CBE) supplements, as well as annual reportable hanges not in luded in the en losed labeling.

[1] http://www.fda.gov/ForIndustry/Data tandards/ tru turedProdu tLabeling/default.htm c

Inform ation on submitting L files using eList m ay be found in the guid nce for industry *SPL Standard for Content of Labeling Technical Qs and As.*[2]

The L will be ccessible from publicly v il ble l beling repositories.
Also within 14 d ys, mend ll pending supplement l pplic tions th t include l beling ch nges for this NDA, including CBE supplements for which FDA h s not yet issued n ction letter, with the content of l beling [21 CFR 314.50(l)(1)(i)] in Microsoft Word form at, th t includes the ch nges pproved in this supplement l pplic tion, s well s nnu l report ble ch nges. To f cilit te review of your submission, provide highlighted or m arked up copy th t shows ll ch nges, s well s cle n Microsoft Word version. The m arked up copy should provide ppropri te nnot tions, including supplement number(s) nd nnu l report d te(s).

CARTON AND CONTAINER LABELING

ubmit fin l printed c rton nd cont iner l beling th t re identic l to c rton nd cont iner l beling submitted on December 9, 2022, s soon s they re v il ble, but no more th n 30 d ys fter they re printed. le se submit these l beling electronic lly ccording to the guid nce for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For dministr tive purposes, design te this submission "**Product Corre pondence – Final Printed Carton and Container Labeling for approved NDA #019101/ S-060**." Approv l of this submission by FDA is not required before the l beling is used.

PROMOTIONAL MATERIALS

You m ay request dvisory comments on proposed introductory dvertising nd promotion l l beling. For inform ation bout submitting promotion l m ateri ls, see the fin l guid nce for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format – Promotional Labeling and Advertisign in Materials for Human Prescription Drugs*.[3]

You must submit fin l promotion l m ateri ls nd rescribing Inform ation, ccomp nied by Form FDA 2253, t the time of initi l dissemin tion or public tion [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is v il ble t FDA.gov.[4] Inform ation nd Instructions for completing the form c n be found t FDA.gov.[5]

---

[2] We upd te guid nces periodic lly. For the most recent version of guid nce, check the FDA Guid nce Documents D t b se https://www.fd .gov/Regul toryInform ation/Guid nces/def ult.htm.
[3] For the most recent version of guid nce, check the FDA guid nce web p ge thttps://www.fd .gov/medi /1281 3/downlo d. s
[4] http://www.fd .gov/downlo ds/AboutFDA/ReportsM anu lsForms/Forms/UCM083570.pdf
[5] http://www.fd .gov/downlo ds/AboutFDA/ReportsM anu lsForms/Forms/UCM375154.pdf

PATENT LISTING REQUIREMENTS

ursu nt to 21 CFR 314.53(d)(2) nd 314.70(f), cert in ch nges to n pproved NDA submitted in supplement require you to submit p tent inform ation for listing in the Or nge Book upon pprov l of the supplement. You must submit the p tent inform ation required by 21 CFR 314.53(d)(2)(i)(A) through (C) nd 314.53(d)(2)(ii)(A) nd (C), s pplic ble, to FDA on Form FDA 3542 within 30 d ys fter the d te of pprov l of the supplement for the p tent inform ation to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You lso must ensure th t ny ch nges to your pproved NDA th t require the submission of request to remove p tent inform ation from the Or nge Book re submitted to FDA t the time of pprov l of the supplement pursu nt to 21 CFR 314.53 (d)(2)(ii)(B) nd 314.53 (f)(2)(iv).

We remind you th t you must comply with the requirements for n pproved NDA set forth under 21 CFR 314.80 nd 314.81.

If you h ve ny questions, ple se cont ct J ne Mun, Regul tory roject M an ger, vi em ail t J ne.Mun@fd .hhs.gov.

s

incerely,

{See appended electronic signature page} s

Rigoberto Roc , MD
Director
Division of Anesthesiology, Addiction Medicine nd in Medicine
Office of Neuroscience
Center for Drug Ev lu tion nd Rese rch

s

ENCLO SURE( ):

- Content of L beling
- C rton nd Cont iner L beling s

This is a r r s a i f a B l c r ic r c rd ha was sig d l c r ically. F ll wi g his ar ma if s a i s f a y a d all l c r ic sig a ur s f r his l c r ic r c rd.

/s/ B

RIGO ERTO A ROCA
01/20/2023 08:01:19 PM