

NDA 021887/S-013

## SUPPLEMENT APPROVAL

Haleon US Holdings LLC  
Attention: Misha C. Mehta  
Senior Associate, US Regulatory Affairs  
184 Liberty Corner Road, Suite 200  
Warren, NJ 07059

Dear Misha Mehta:

Please refer to your supplemental new drug application (sNDA) dated and received October 14, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Alli (orlistat) capsule, 60 mg.

This “Changes Being Effected” sNDA provides for safety related changes as requested in FDA’s September 17, 2025, CBE-0 Supplement Request letter. The revised Drug Facts Label includes the following:

- Under the section **Ask a Doctor Before Use if you have** ever had, the term “kidney disease” was added
- Under the section **Stop Use and Ask a Doctor If**, the bullet “you develop severe pain in the back or groin, painful urination, blood in your urine, swelling of the legs or feet, or are urinating less often than normal. There have been rare reports of kidney injury in people taking orlistat” was added

### **APPROVAL & LABELING**

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

### **LABELING**

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling, as submitted on January 14, 2026, and as described in the table below and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

<b>Submitted Labeling</b>	<b>Date of Submission</b>
Alli 60 Capsules Draft Carton	January 14, 2026
Alli 60 Capsules Draft Inner Label	January 14, 2026
Alli 120 Capsules Draft Carton	January 14, 2026

Alli 120 Capsules Draft Inner Label	January 14, 2026
Alli 170 Capsules Draft Carton	January 14, 2026
Alli 170 Capsules Draft Inner Label	January 14, 2026

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 021887/S-013.**” Approval of this submission by FDA is not required before the labeling is used.

## **DRUG REGISTRATION AND LISTING**

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at FDA.gov.<sup>2</sup> 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*. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

## **REPORTING REQUIREMENTS**

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

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<sup>1</sup> 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>.

<sup>2</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

If you have any questions, contact Kristen Leazer, Senior Regulatory Health Project Manager, at [Kristen.Leazer@fda.hhs.gov](mailto:Kristen.Leazer@fda.hhs.gov) or 240-402-1418.

Sincerely,

*{See appended electronic signature page}*

Amy Weitach, D.O., M.S.  
Deputy Director for Safety  
Division of Nonprescription Drugs II  
Office of Nonprescription Drugs  
Office of New Drugs  
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

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**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.**  
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/s/  
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