NDA 018989/S-104

SUPPLEMENT APPROVAL

Haleon US Holdings LLC
Attention: Alberto Jose Garzon
Senior Regulatory Affairs Manager, US Regulatory
184 Liberty Corner Road
Suite 200
Warren, NJ 07059

Dear Alberto Jose Garzon:

Please refer to your supplemental new drug application (sNDA) dated and received September 10, 2024, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil (ibuprofen) tablets, 200 mg.

This prior approval supplemental new drug application provides for the addition of the following new stock-keeping units (SKUs):

- 120-count (12 x 10-count) vial dispenser
- 200-count (2 x 100-count) twin pack

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.

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 in the "Drug Facts" format (21 CFR 201.66), where applicable and must be identical to the following labeling:

Submitted Labeling	Date Submitted
120-count (12 x 10-count) vial dispenser	November 18, 2024
200-count (2 x 100-count) twin pack (value pack)	December 4, 2024

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*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 018989/S-104**." 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.[2] 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).

If you have any questions, contact Myla Dellupac, Regulatory Project Manager, at Myla.Dellupac@fda.hhs.gov or 301-837-7461.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

[1] 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.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

ENCLOSURE(S):

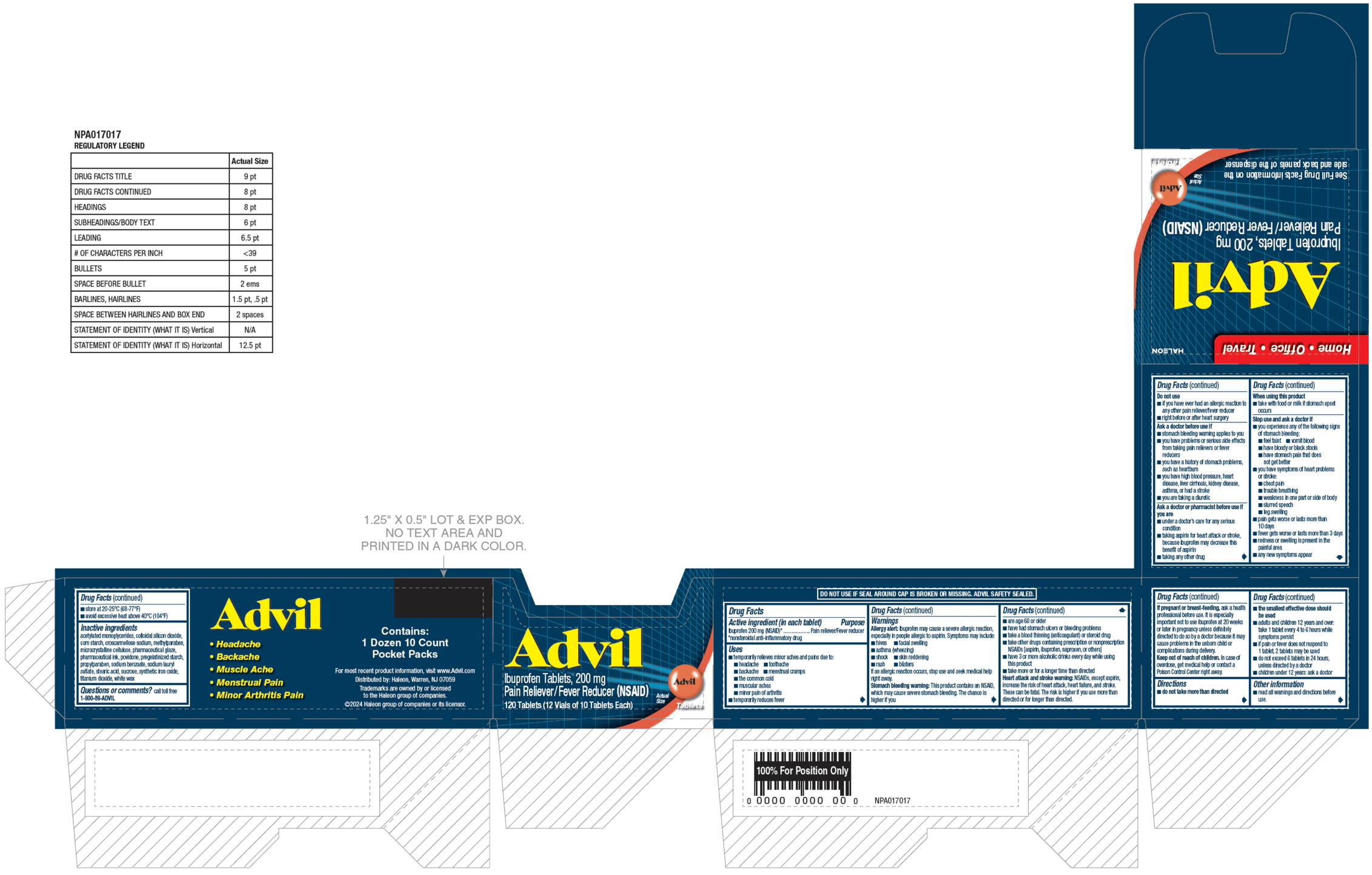
- Carton Labeling

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

NPA017017
REGULATORY LEGEND

	Actual Size
DRUG FACTS TITLE	9 pt
DRUG FACTS CONTINUED	8 pt
HEADINGS	8 pt
SUBHEADINGS/BODY TEXT	6 pt
LEADING	6.5 pt
# OF CHARACTERS PER INCH	<39
BULLETS	5 pt
SPACE BEFORE BULLET	2 ems
BARLINES, HAIRLINES	1.5 pt, .5 pt
SPACE BETWEEN HAIRLINES AND BOX END	2 spaces
STATEMENT OF IDENTITY (WHAT IT IS) Vertical	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Horizontal	12.5 pt

1.25" X 0.5" LOT & EXP BOX.
NO TEXT AREA AND
PRINTED IN A DARK COLOR.



14-15/32"

128 CODE AREA - SUBSET C 10MIL DENSITY
WITH 4 OR 6 DIGITS (CODE TO EXTEND TO EDGE OF FLAP)
UNVARNISHED - PRINTED SIDE OF CARTON

128 CODE AREA

NO VARNISH - GLUE AREA

128 CODE AREA

NO VARNISH - GLUE AREA

128 CODE AREA

NO VARNISH - GLUE AREA

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

Active ingredient (in each tablet) — **Purpose**

Ibuprofen 200 mg (NSAID)* ..... Pain reliever/Fever reducer

*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - toothache
  - backache
  - menstrual cramps
  - the common cold
  - muscular aches
  - minor pain of arthritis
- temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and over: take 1 tablet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 tablet, 2 tablets may be used
- do not exceed 6 tablets in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- read all warnings and directions before use. Keep carton.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients acetylated monoglycerides, colloidal silicon dioxide, corn starch, croscarmellose sodium, methylparaben, microcrystalline cellulose, pharmaceutical glaze, pharmaceutical ink, povidone, pregelatinized starch, propylparaben, sodium benzoate, sodium lauryl sulfate, stearic acid, sucrose, synthetic iron oxide, titanium dioxide, white wax

Questions or comments? call toll free **1-800-88-ADVIL**

Advil

VALUE PACK
2x100 Count

RELIEF AT HOME & ON-THE-MOVE

VALUE PACK 2x100 Count

Advil

Ibuprofen Tablets, 200 mg
Pain Reliever/Fever Reducer **(NSAID)**

Actual Size

***200** Tablets*
***2x100** Count Bottles Inside*

VALUE PACK 2x100 Count

Advil

Ibuprofen Tablets, 200 mg
Pain Reliever/Fever Reducer **(NSAID)**

***2x100** Count Bottles Inside*

Actual Size

Do Not Use if seal under bottle cap imprinted with *"SEALED for YOUR PROTECTION"* is broken or missing.

Distributed by: Haleon, Warren, NJ 07059
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214563

FPO

3 0573655974 8

9-1/4"

OUTSIDE BLEED

PRINTED AREA FOR DATE & LOT LASER CODING (VARNISHED)

214563

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
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• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

Reference ID: 5504230

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/

NUSHIN F TODD
12/30/2024 01:20:51 PM