ATTACHMENT C

CENTER FOR DRUG EVALUATION AND RESEARCH

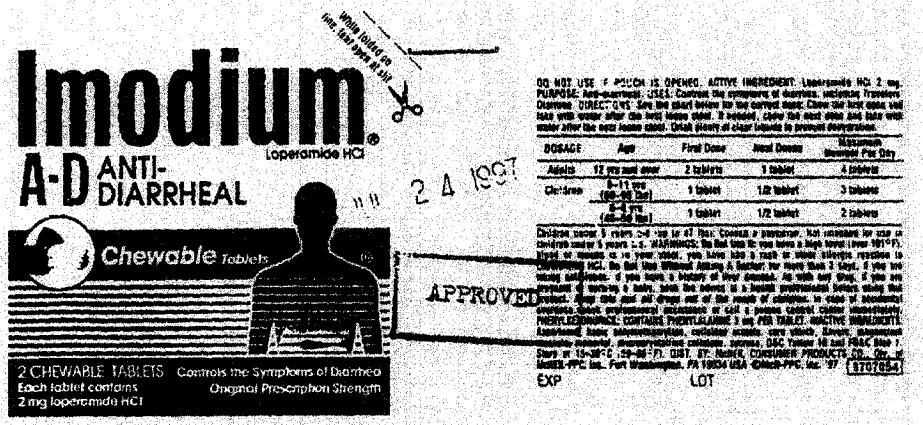
Application Number 20-448

FINAL PRINTED LABELING

Labeling: _____

NDA No: _____ Rc'd. _____

Reviewed by: _____



APPEARS THIS WAY
ON ORIGINAL

INACTIVE INGREDIENTS: Aspartame, basic polymethacrylate, cellulose acetate, corn starch, flavors, magnesium stearate, mannitol, microcrystalline cellulose, sucrose, D&C Yellow #10 and FD&C Blue #1

McNEIL

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McNEIL CONSUMER PRODUCTS CO.
DIVISION OF McNEIL-PPC, INC.
FORT WASHINGTON, PA 19034 USA

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Imodium® A-D ANTI-DIARRHEAL loperamide HCl **Chewable** tablets

EXP

LOT

Imodium® loperamide HCl **A-D ANTI-DIARRHEAL** **Chewable** tablets

NEW!

6 CHEWABLE TABLETS

Controls the Symptoms of Diarrhea
Original Prescription Strength

Do not responsibly is to you and your family. That is why we guarantee that all MOTRIN® A-D products meet stringent standards for purity, quality and consistency. If you are not completely satisfied with any product, return it to the seller with an invoice or receipt, the product and we will refund it at your choice or refund the purchase price.

For your safety and convenience, this package is child-resistant. Please follow instructions on the package to open your product. Please follow instructions on the package of the blister card to open the product. Blister card is more difficult to open vs. a bottle.

Imodium® loperamide HCl **A-D ANTI-DIARRHEAL** **Chewable** tablets

6 CHEWABLE TABLETS

Controls the Symptoms of Diarrhea, including Travelers' Diarrhea.

APPROVED

9707051

DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS BROKEN.

Only from the makers of Imodium® A-D, Chewable Tablets:

- **are uniquely formulated and convenient to take anywhere**
- **contain the original prescription strength of Imodium® A-D for diarrhea relief, often in just one dose**

ACTIVE INGREDIENT: Loperamide HCl 2 mg • **PURPOSE:** Anti-diarrheal

USES • Controls the symptoms of diarrhea, including Travelers' Diarrhea

DIRECTIONS See the chart below for the correct dose
- Chew the first dose and take with water after the first loose stool
- If needed, chew the next dose and take with water after the next loose stool
- Drink plenty of clear liquids to prevent dehydration.

DOSAGE	Age	First Dose	Next Doses	Maximum Number Per Day
Adults	12 yrs and over	2 tablets	1 tablet	4 tablets
Children	9–11 yrs (60–95 lbs)	1 tablet	1/2 tablet	3 tablets
	6–8 yrs (48–59 lbs)	1 tablet	1/2 tablet	2 tablets

Children under 6 years old (up to 47 lbs): Consult a physician. Not intended for use in children under 6 years old.

WARNINGS
- **Do Not Use If:**
  - You have a high fever (over 101°F)
  - Blood or mucus in your stool
  - You have had a rash or other allergic reaction to Loperamide HCl
- **Do Not Use Without Asking A Doctor:**
  - For more than 2 days
  - If you are taking antibiotics
  - If you have a history of liver disease

As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

- ***Keep this and all drugs out of the reach of children.***
- In case of accidental overdose, seek professional assistance or contact a poison control center immediately.
- PHENYLKETONURICS: CONTAINS PHENYLALANINE 3 mg PER TABLET

Store at 15–30°C (59–86°F)

2 4

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Reviewed by: _____

NDA No: _____

Lot: _____