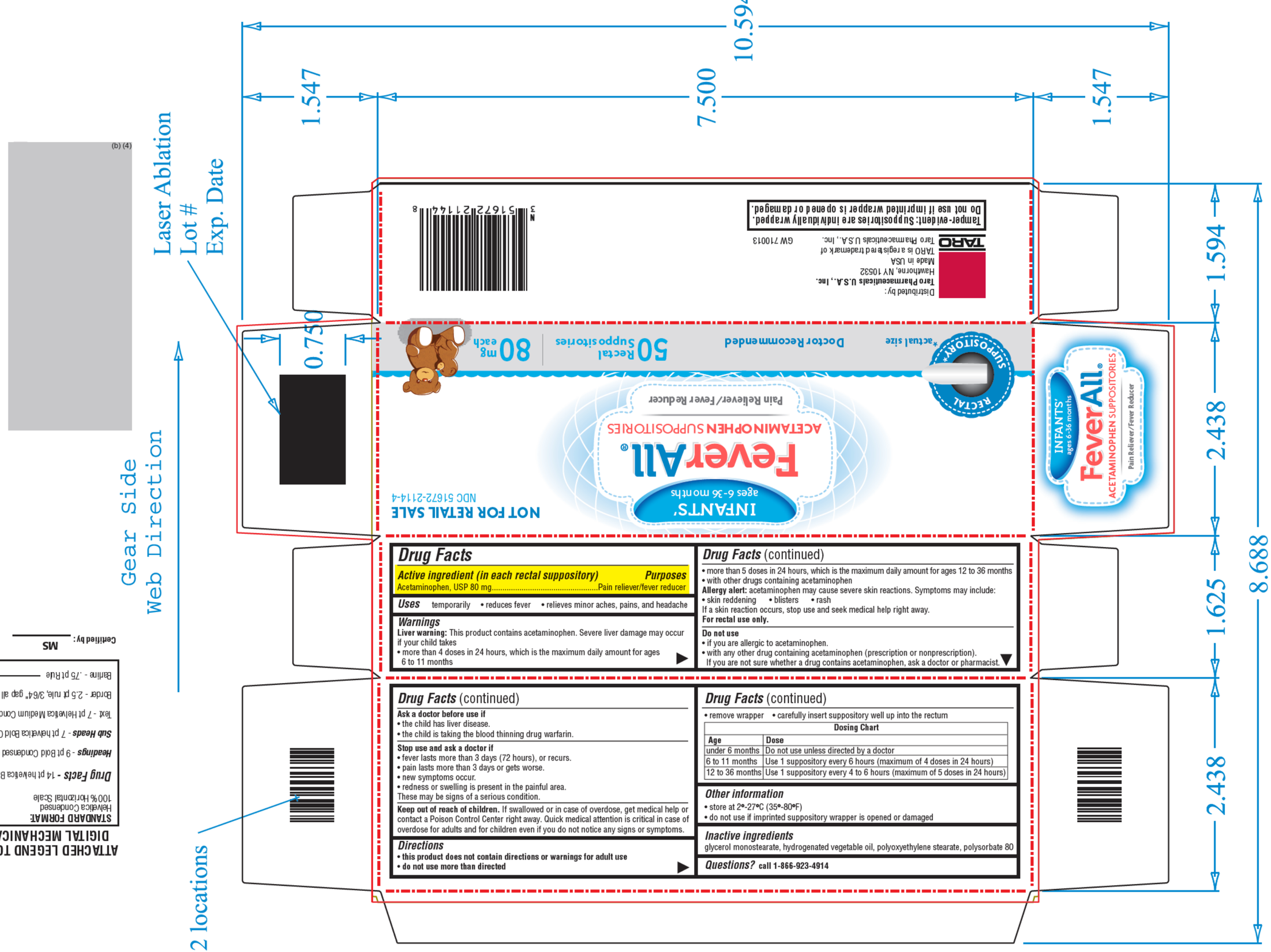
Z-Folded
10.250
2.500 (Length)
1.000 (Width)
1.648
0.937
3.313 (Depth)
0.937
5.187
4.102
1.000
0.906
0.750
0.107
(2plcs) Not actual code
Code bars to be changed
to match this product
Laser Ablation
Lot #
Exp. Date
NDC 51672-2114-2
RECTAL SUPPOSITORY*
Doctor Recommended
Pain Reliever/Fever Reducer
*actual size
INFANTS' ages 6-36 months
FeverAll.
ACETAMINOPHEN SUPPOSITORIES
Pain Reliever/Fever Reducer
6 Rectal Suppositories
80 mg each
Dist. by: Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532
Made in USA
GW 71001O
Tamper-evident: Suppositories are individually wrapped.
Do not use if imprinted wrapper is opened or damaged.
Drug Facts
Active ingredient (in each rectal suppository)
Acetaminophen, USP 80 mg
Purposes
Pain reliever/fever reducer
Uses temporarily • reduces fever • relieves minor aches, pains, and headache
Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes
• more than 4 doses in 24 hours, which is the maximum daily amount for ages 6 to 11 months
• more than 5 doses in 24 hours, which is the maximum daily amount for ages 12 to 36 months
• with other drugs containing acetaminophen
Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:
• skin reddening • blisters • rash
If a skin reaction occurs, stop use and seek medical help right away.
For rectal use only.
Do not use
• if you are allergic to acetaminophen.
• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
Ask a doctor before use if
• the child has liver disease.
• the child is taking the blood thinning drug warfarin.
Stop use and ask a doctor if
• fever lasts more than 3 days (72 hours), or recurs.
• pain lasts more than 3 days or gets worse.
• new symptoms occur.
• redness or swelling is present in the painful area.
These may be signs of a serious condition.
Drug Facts (continued)
Keep out of reach of children. If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for adults and for children even if you do not notice any signs or symptoms.
Directions • this product does not contain directions or warnings for adult use
• do not use more than directed
• remove wrapper
• carefully insert suppository well up into the rectum
Dosing Chart
Age | Dose
under 6 months | Do not use unless directed by a doctor
6 to 11 months | Use 1 suppository every 6 hours (maximum of 4 doses in 24 hours)
12 to 36 months | Use 1 suppository every 4 to 6 hours (maximum of 5 doses in 24 hours)
Other information
• store at 2°-27°C (35°-80°F)
• do not use if imprinted suppository wrapper is opened or damaged
Inactive ingredients
glycerol monostearate, hydrogenated vegetable oil, polyoxyethylene stearate, polysorbate 80
Questions? call 1-866-923-4914
ATTACHED LEGEND TO ALL
DIGITAL MECHANICALS
STANDARD FORMAT:
Helvetica Condensed
90% Horizontal Scale
Drug Facts - 10 pt helvetica Bold Condensed Oblique
Headings - 8 pt Bold Condensed Oblique
Sub Heads - 6 pt helvetica Bold Condensed
Text - 6 pt Helvetica Medium Condensed
Border - 1 pt rule, 3/64" gap all around
Barline - 1 pt Rule
Certified by: MS



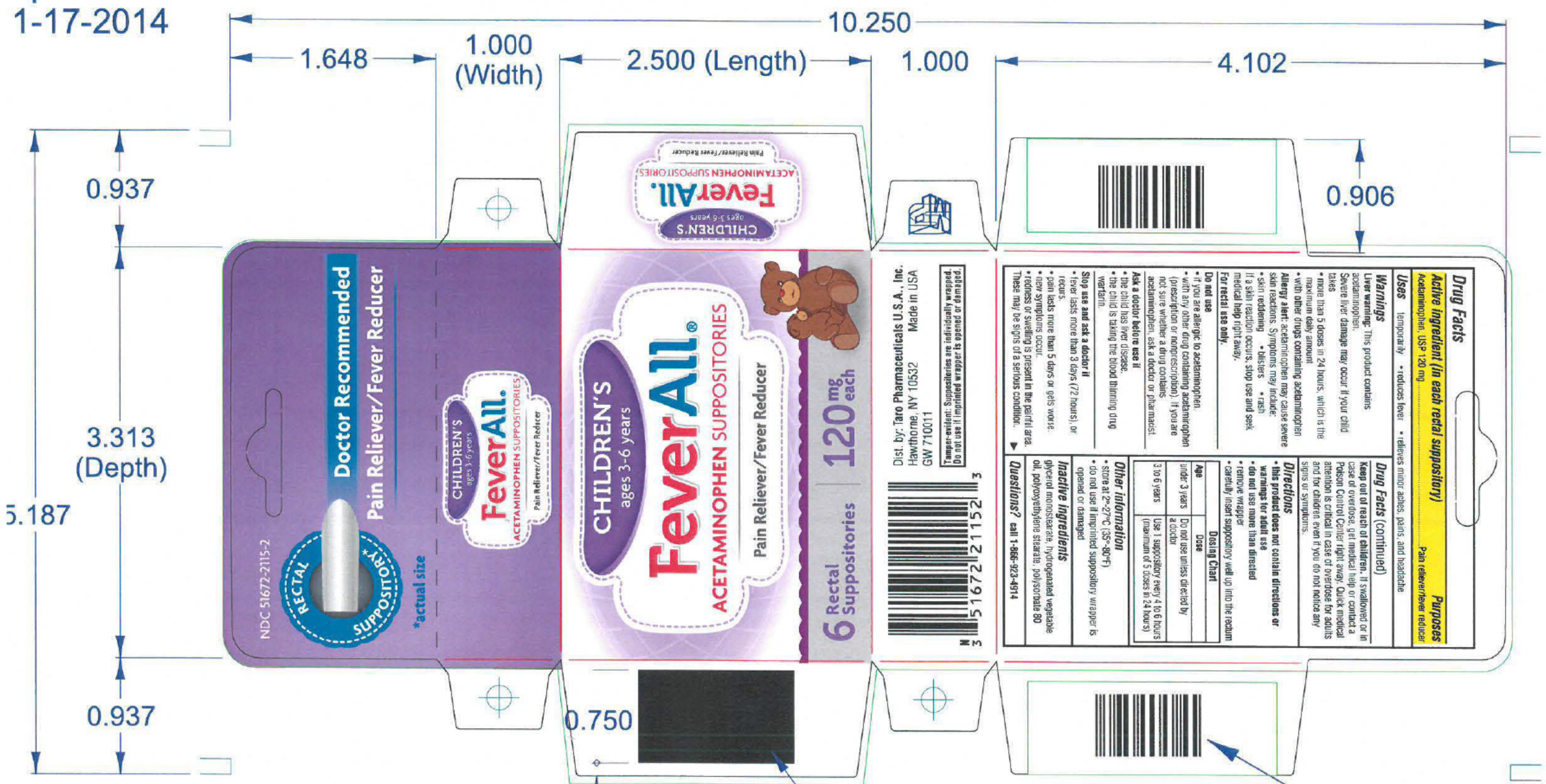
Reference ID: 3805210

.10272A2

(b) (4)

Feverall 5th PNL CTN
2.500' x 1.000" x 1.648"
5pt C1S SBS
1-17-2014

Z-Folded



(b) (4)

ATTACHED LEGEND TO ALL DIGITAL MECHANICALS

STANDARD FORMAT:
Helvetica Condensed
90% Horizontal Scale

Drug Facts - 10 pt helvetica Bold Condensed Oblique

Headings - 8 pt Bold Condensed Oblique

Sub Heads - 6 pt helvetica Bold Condensed

Text - 6 pt Helvetica Medium Condensed

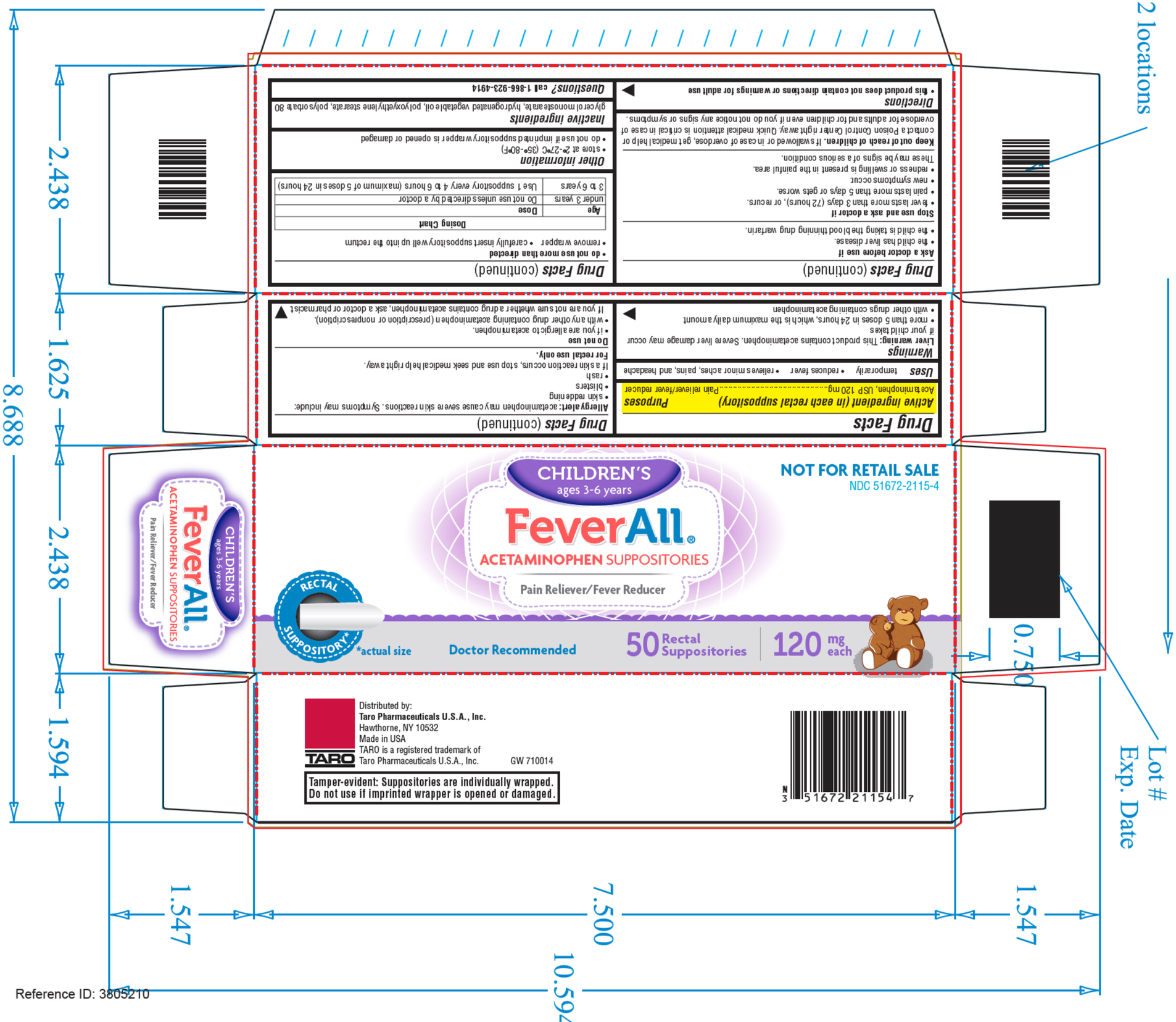
Border - 1 pt rule, 3/64" gap all around

Barline - 1 pt Rule

Certified by: MS

(b) (4)

Reference ID: 3805210



Drug Facts

Active ingredient (in each rectal suppository) — **Purposes**

Acetaminophen, USP 120 mg ..... Pain reliever/fever reducer

Uses temporarily • reduces fever • relieves minor aches, pains, and headache

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes
• more than 5 doses in 24 hours, which is the maximum daily amount
• with other drugs containing acetaminophen

Drug Facts (continued)

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:
• skin reddening
• blisters
• rash
If a skin reaction occurs, stop use and seek medical help right away.

For rectal use only.

Do not use
• if you are allergic to acetaminophen.
• with any other drug containing acetaminophen (prescription or nonprescription).
If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

Drug Facts (continued)

Ask a doctor before use if
• the child has liver disease.
• the child is taking the blood thinning drug warfarin.

Stop use and ask a doctor if
• fever lasts more than 3 days (72 hours), or recurs.
• pain lasts more than 5 days or gets worse.
• new symptoms occur.
• redness or swelling is present in the painful area.
These may be signs of a serious condition.

Keep out of reach of children. If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for adults and for children even if you do not notice any signs or symptoms.

Directions
• this product does not contain directions or warnings for adult use

Drug Facts (continued)

• **do not use more than directed**
• remove wrapper • carefully insert suppository well up into the rectum

Dosing Chart

Age	Dose
under 3 years	Do not use unless directed by a doctor
3 to 6 years	Use 1 suppository every 4 to 6 hours (maximum of 5 doses in 24 hours)

Other information
• store at 2°-27°C (35°-80°F)
• do not use if imprinted suppository wrapper is opened or damaged

Inactive ingredients
glycerol monostearate, hydrogenated vegetable oil, polyoxyethylene stearate, polysorbate 80

Questions? call 1-866-923-4914

ATTACHED LEGEND TO ALL DIGITAL MECHANICALS

STANDARD FORMAT:
Helvetica Condensed
100% Horizontal Scale

Drug Facts - 14 pt helvetica Bold Condensed Oblique

Headings - 9 pt Bold Condensed Oblique

Sub Heads - 7 pt helvetica Bold Condensed

Text - 7 pt Helvetica Medium Condensed

Border - 2.5 pt rule, 3/64" gap all around

Barline - .75 pt Rule

Certified by: MS

(b) (4)

Reference ID: 3805210

L10272A2

(b) (4)

Feverall 5th PNL CTN
2.500' x 1.000" x 1.648"
15pt C1S SBS
11-17-2014

Z-Folded

(b) (4)

ATTACHED LEGEND TO ALL DIGITAL MECHANICALS

STANDARD FORMAT:
Helvetica Condensed
90% Horizontal Scale

Drug Facts - 10 pt helvetica Bold Condensed Oblique

Headings - 8 pt Bold Condensed Oblique

Sub Heads - 6 pt helvetica Bold Condensed

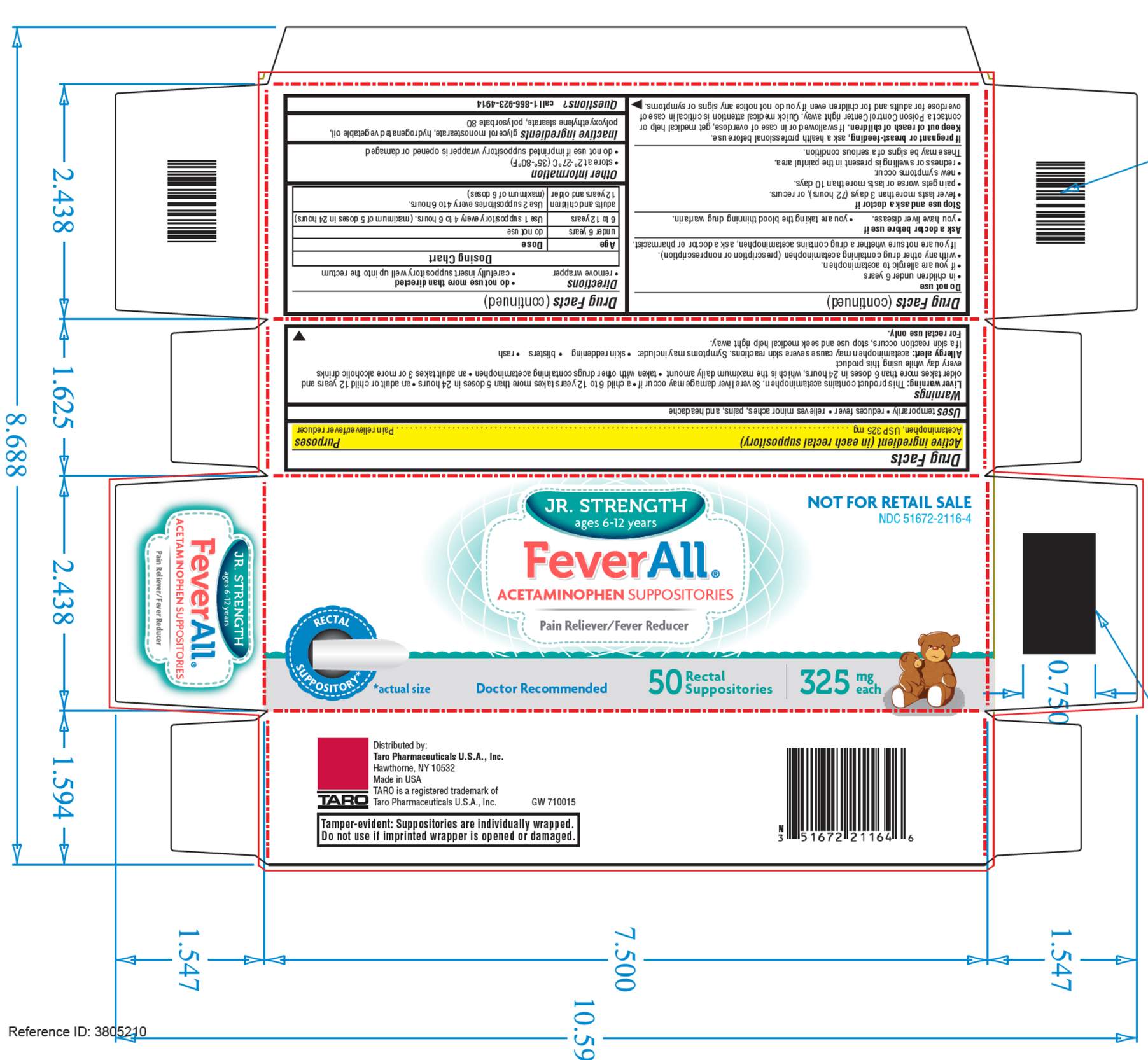
Text - 6 pt Helvetica Medium Condensed

Border - 1 pt rule; 3/64" gap all around

Barline - 1 pt Rule _____

Certified by: MS

Reference ID: 3805210



ATTACHED LEGEND TO ALL DIGITAL MECHANICALS

STANDARD FORMAT:
Helvetica Condensed
100% Horizontal Scale

Drug Facts - 12 pt helvetica Bold Condensed Oblique

Headings - 9 pt Bold Condensed Oblique

Sub Heads - 7 pt helvetica Bold Condensed

Text - 7 pt Helvetica Medium Condensed

Border - 2.5 pt rule, 3/64" gap all around

Barline - .75 pt Rule

Certified by: MS

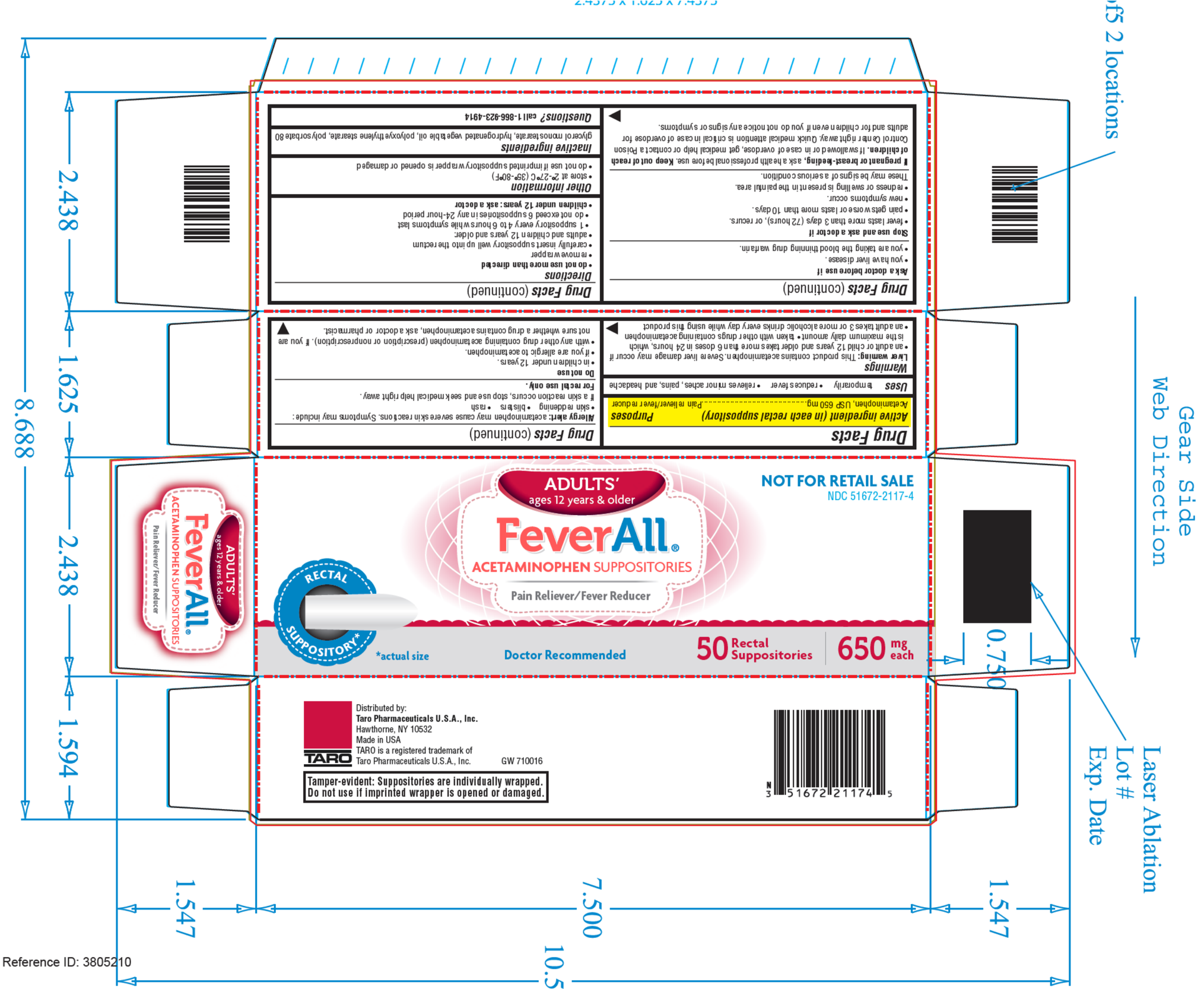
(b) (4)

DATE	LPK#	ART COPY CTRL.#
PASS#	UPC#	

DEPARTMENT	SIGNATURE	NO	YES	DATE
PROOFING				
ART				
MARKETING				
ENGINEERING				
Q.C.				
REG.				
MEDICAL OFFICER				
CLIENT				

THIS COLOR PROOF INDICATES COLOR BREAK ONLY AND MAY NOT ACCURATELY REFLECT ACTUAL PRODUCTION COLOR
IF YOU HAVE ANY QUESTIONS OR COMMENTS PLEASE CALL TARO PHARMACEUTICALS-ART DEPARTMENT 800-544-1449.

Reference ID: 3805210



ATTACHED LEGEND TO ALL DIGITAL MECHANICALS

STANDARD FORMAT:
Helvetica Condensed
100% Horizontal Scale

Drug Facts - 14 pt helvetica Bold Condensed Oblique

Headings - 9 pt Bold Condensed Oblique

Sub Heads - 7 pt helvetica Bold Condensed

Text - 7 pt Helvetica Medium Condensed

Border - 2.5 pt rule, 3/64" gap all around

Barline - .75 pt Rule

Certified by: MS

Reference ID: 3805210

SUPPOSITORY SIDE BY SIDE COMPARISON

CURRENT DRUG LABELING	**80 mg**	**PROPOSED DRUG LABELING**

(b) (4)

1. Changed color scheme and design
2. Bar code and numbers revised from Actavis to Taro's.
3. Updated Distributor statement from Actavis to Taro's.

Reference ID: 3805210

CURRENT DRUG LABELING **120 mg** **PROPOSED DRUG LABELING**

1. Changed color scheme and design. (b) (4)
2. Bar code number revised from Actavis to Taro's.
3. Updated Distributor statement from Actavis to Taro's.

CURRENT DRUG LABELING **325 mg** **PROPOSED DRUG LABELING**

1. Changed color scheme and design. (b) (4)
2. Added Jr. Strength before 325mg.
3. Bar code number revised from Actavis to Taro's.
4. Updated Distributor statement from Actavis to Taro's.

Reference ID: 3805210

CURRENT DRUG LABELING **650 mg** **PROPOSED DRUG LABELING**

1. No change to colors.
2. Bar code number revised from Actavis to Taro's.
3. Updated Distributor statement from Actavis to Taro's.

FeverAll®
Acetaminophen Suppositories
Pain reliever/fever reducer

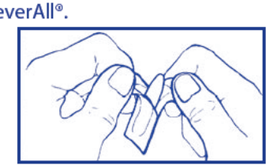
FeverAll®

Acetaminophen Suppositories

Pain reliever/fever reducer

FPO

DIRECTIONS: When practical, cleanse area around rectum with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before using FeverAll®.



1. Remove wrapper before inserting suppository as follows: hold suppository upright and carefully separate wrapper at pointed end to open.
2. Carefully peel wrapper down both sides evenly, exposing suppository.
3. Avoid excess handling, as suppository is designed to melt at body temperature. Suppositories should not need to be refrigerated if stored below 80ºF (27ºC).
4. Place child flat on back or on side with anal opening exposed.
5. Insert suppository gently, well into rectum. Use fingertip to complete insertion.

Questions? call 1-866-923-4914

Dist by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532
Made in USA

(b) (4)

ATTACHED LEGEND TO ALL DIGITAL MECHANICALS

STANDARD FORMAT:
Myriad Pro
100% Horizontal Scale

Heads - 10 pt Myriad Pro bold

Text - 10 pt Myriad Pro regular

Certified by: MS

Reference ID: 3805210

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN M MAHONEY
08/12/2015