

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-267/S-009

Trade Name: Lwplqt Utgpi vj Cf xkn

Generic Name: Kwr tqhgp

Sponsor: Y {gyj Eqpuwo gt J gcmj ectg

Approval Date: August 30, 2004

Supplement Changes: vj g cf f kkp qhc õuxqo cej drggf kpi y ctpkpi ö cpf qti cp/ur gekle y ctpkpi u vq vj g rdgnkpi 0

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APPLICATION NUMBER:
NDA 20-267/S-009

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APPLICATION NUMBER:

NDA 20-267/S-009

APPROVAL LETTER



NDA 20-267/S-009

Wyeth Consumer Healthcare
Attention: Lauren Quinn
Associate Director, Regulatory Affairs
Five Giralda Farms
Madison, New Jersey 07940

Dear Ms. Quinn:

Please refer to your supplemental new drug application dated March 2, 2004, received March 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Junior Strength Advil (100 mg ibuprofen) tablets.

This "Changes Being Effected" supplemental new drug application provides for the addition of new organ-specific warnings to the Drug Facts label.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 2, 2004, for the 24 count tablets (carton and bottle).

Implement the following changes to the carton PDP at the time of next printing.

1. Place the statement of identity (Ibuprofen Tablets, 100 mg, Fever Reducer/Pain Reliever) immediately adjacent to (i.e., under) the proprietary name in accordance with 21 CFR 201.61(b).
2. Increase the font size of the statement of identity in accordance with 21 CFR 201.61(c).

We are concerned about the need for organ-specific warnings for OTC drug products containing analgesic/antipyretic active ingredients. The proposed stomach bleeding warning is acceptable as interim language. However, please note that we will be providing guidance on wording and placement of organ-specific warnings in the labeling of drug products containing NSAIDs in the future.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

NDA 20-267/S-009

Page 2

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Walter Ellenberg, Ph.D., Regulatory Project Manager, at (301) 827-2241.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.

Director

Division of Over-the-Counter Drug Products

Office of Drug Evaluation V

Center for Drug Evaluation and Research

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

/s/

Charles Ganley
8/30/04 02:59:08 PM

**CENTER FOR DRUG EVALUATION AND
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APPLICATION NUMBER:
NDA 20-267/S-009

LABELING

AUG 30 2004

APPROVED

Labeling: 3LR-009

NDA No 20-267 Rec'd 3-3-04

Reviewed by: *McKeeney*
3-17-04

See box for important information and save for future use.

Active ingredient (in each tablet)
Ibuprofen 100 mg

Purposes
Fever reducer/Pain reliever

Uses temporarily: ■ reduces fever ■ relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

Warnings
Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: ■ hives ■ asthma (wheezing) ■ facial swelling ■ shock

Stomach bleeding warning: Taking more than recommended may cause stomach bleeding. **Sore throat warning:** Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor. Do not use if the child has ever had an allergic reaction to any other fever reducer/pain reliever. Stop use and ask a doctor if an allergic reaction occurs. Seek medical help right away.

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

Junior Strength
Advil
Fever Reducer/Pain Reliever

24 COATED TABLETS

Directions ■ Do not give more than directed ■ Find right dose on chart below. If possible, use weight to dose; otherwise use age. ■ Repeat dose every 6-8 hours, if needed ■ Do not use more than 4 times a day

Dosing Chart

Weight (lb)	Age (yr)	Dose (tablets)
under 48 lb	under 6 yr	ask a doctor
48-71 lb	6-10 yr	2 tablets
72-95 lb	11 yr	3 tablets

Use Dose Labels 6-8 Hours
Store at 20-25°C (68-77°F)
Questions or comments? Call toll-free 1-800-86-ADVIL or ask your pharmacist, doctor or health care professional.

Weylan Consumer Healthcare, Madison, NJ 07940

30 2004

U0175-10-N1



APPROVED

Drug Facts (continued)

Do not use if the child has ever had an allergic reaction to any other fever reducer/pain reliever

Ask a doctor before use if the child has ■ not been drinking fluids ■ ulcers ■ bleeding problems ■ lost a lot of fluid due to continued vomiting or diarrhea ■ problems or serious side effects from taking fever reducers or pain relievers ■ stomach problems that last or come back, such as heartburn, upset stomach or pain ■ high blood pressure, heart or kidney disease or is taking a diuretic

Ask a doctor or pharmacist before use if the child is ■ under a doctor's care for any serious condition ■ taking any other product that contains ibuprofen, or any other pain reliever/fever reducer ■ taking a prescription product for anticoagulation (blood thinning) ■ taking any other drug

When using this product give with food or milk if stomach upset occurs

Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away. ■ fever or pain gets worse or lasts more than 3 days

AUG 30 2004

Drug Facts (continued)

Stop use and ask a doctor if ■ the child does not get any relief within first day (24 hours) of treatment ■ stomach pain or upset gets worse or lasts ■ redness or swelling is present in the painful area ■ any new symptoms appear

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

Directions ■ do not give more than directed ■ find right dose on chart below. If possible, use weight to dose; otherwise use age. ■ repeat dose every 6-8 hours, if needed ■ do not use more than 4 times a day

Dosing Chart

Weight (lb)	Age (yr)	Dose (tablets)
under 48 lb	under 6 yr	ask a doctor
48-71 lb	6-10 yr	2 tablets
72-95 lb	11 yr	3 tablets

3 0573-0175-10 4

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

Junior Strength
Advil
Easy to Swallow Tablets
Ibuprofen Tablets 100 mg

Fever
Aches & Pains Lasts Up To **8** Hours

for ages 6-11 years

24 COATED TABLETS

Weylan Consumer Healthcare, Madison, NJ 07940

Drug Facts (continued)

Other information: ■ one dose lasts 6-8 hours ■ store at 20-25°C (68-77°F) ■ see side of box for or number and expiration date

Inactive ingredients: activated monoglycerides, carmellose, colloidal silicon dioxide, croscarmellose sodium, iron oxides, methacrylates, microcrystalline cellulose, polydextrose, pregelatinized starch, propylene glycol, polyvinylpyrrolidone, stearic acid, sodium bicarbonate, stearic acid, sucrose, titanium dioxide

Questions or comments? Call toll-free 1-800-86-ADVIL or ask your pharmacist, doctor or health care professional

Important: Read all product information before using. Keep this carton for important information. This product is intended for use in children ages 6 years-11 years

Drug Facts

Active ingredient (in each tablet) ■ Fever reducer/Pain reliever

Ibuprofen 100 mg

Uses temporarily: ■ reduces fever ■ relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

Warnings
Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: ■ hives ■ asthma (wheezing) ■ facial swelling ■ shock

Stomach bleeding warning: Taking more than recommended may cause stomach bleeding. **Sore throat warning:** Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.

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**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

NDA 20-267/S-009

LABELING REVIEW



OTC Drug Labeling Review for Junior Strength Advil[®] Tablets

Division of Over-The-Counter Drug Products (HFD-560)
Center for Drug Evaluation and Research • Food and Drug Administration

SUBMISSION DATE(S):	March 2, 2004	RECEIVED DATE(S):	March 3, 2004
REVIEW DATE:			March 17, 2004
NDA/SUBMISSION TYPE:			NDA 20-267 (SLR-009)
SPONSOR:			Wyeth Consumer Healthcare
DRUG PRODUCT:			Junior Strength Advil Tablets
ACTIVE INGREDIENT:			Ibuprofen, 100 mg
PHARMACOLOGICAL CATEGORY:			Fever reducer/Pain reliever
LABELING SUBMITTED:			Submitted 24 count carton and bottle labels
REVIEWER:			Michael L. Koenig, Ph.D.
TEAM LEADER:			Matthew R. Holman, Ph.D.

BACKGROUND

On August 21, 2002, FDA published a tentative final monograph (TFM) for over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic drug products to include ibuprofen as a generally recognized safe and effective analgesic/antipyretic active ingredient for OTC use. On September 20, 2002, the Nonprescription Drugs Advisory Committee (NDAC) discussed the risks for gastrointestinal bleeding and renal toxicity associated with the use of ibuprofen and other OTC non steroidal anti-inflammatory active ingredients (NSAIDs) and recommended additional warnings be added to the labeling for OTC NSAIDs. In response to the TFM, the NDAC recommendations, and ibuprofen warning changes requested in the December 19, 2002, approval letter for NDA 21-441 (Advil Allergy Sinus Caplets), the sponsor proposes to amend the labeling for Junior Strength Advil Tablets.

REVIEWED LABELING

Carton label

Drug Facts (continued)

Do not use if the child has ever had an allergic reaction to any other fever reducer/pain reliever

Ask a doctor before use if the child has ■ not been drinking fluids ■ ulcers ■ bleeding problems ■ lost a lot of fluid due to continued vomiting or diarrhea ■ problems or serious side effects from taking fever reducers or pain relievers ■ stomach problems that last or come back, such as heartburn, upset stomach or pain ■ high blood pressure, heart or kidney disease or is taking a diuretic

Ask a doctor or pharmacist before use if the child is ■ under a doctor's care for any serious condition ■ taking any other product that contains ibuprofen, or any other pain reliever/fever reducer ■ taking a prescription product for anticoagulation (blood thinning) ■ taking any other drug

When using this product give with food or milk if stomach upset occurs

Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away. ■ fever or pain gets worse or lasts more than 3 days



Drug Facts (continued)

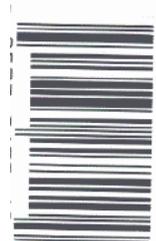
Stop use and ask a doctor if ■ the child does not get any relief within first day (24 hours) of treatment ■ stomach pain or upset gets worse or lasts ■ redness or swelling is present in the painful area ■ any new symptoms appear

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

Directions ■ do not give more than directed ■ find right dose on chart below. If possible, use weight to dose; otherwise use age. ■ repeat dose every 6-8 hours, if needed ■ do not use more than 4 times a day

Dosing Chart

Weight (lb)	Age (yr)	Dose (tablets)
under 48 lb	under 5 yr	ask a doctor
48-71 lb	6-10 yr	2 tablets
72-95 lb	11 yr	3 tablets



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

Junior Strength

Advil®

Easy to Swallow Tablets

Ibuprofen Tablets 100 mg >> Fever Reducer/Pain Reliever

Fever

Aches & Pains

Lasts Up To

8

Hours

ADVIL 100

for ages 6-11 years

24 COATED TABLETS

Wyeth Consumer Healthcare, Madison, NJ 07940

Questions or comments? Call toll-free 1-800-88-ADVIL or ask your pharmacist, doctor or health care professional.

Drug Facts (continued)

Other Information ■ one dose lasts 8 hours ■ store at 20-25°C (68-77°F) ■ see side of box for lot number and expiration date

Inactive ingredients acetylated monoglycerides, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, iron oxides, methylparaben, microcrystalline cellulose, polydextrose, polyethylene glycol, propylparaben, stearic acid, sodium benzoate, starch, stearic acid, sucrose, titanium dioxide

Important: Read all product information before using. Keep this carton for important information. This product is intended for use in children ages 6 years-11 years

Drug Facts

Active ingredient (in each tablet) Ibuprofen 100 mg.....**Purposes** Fever reducer/Pain reliever

Uses temporarily: ■ reduces fever ■ relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: ■ hives ■ asthma (wheezing) ■ facial swelling ■ shock

Stomach bleeding warning: Taking more than recommended may cause stomach bleeding. **Sore throat warning:** Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.

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Summary of proposed changes to **Warnings** section of the Drug Facts panel with changes highlighted in red.

New/Revised Warnings	Previous Warnings
<p>Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:</p> <ul style="list-style-type: none"> • hives • facial swelling • asthma (wheezing) • shock <p>Stomach bleeding warning: Taking more than recommended may cause stomach bleeding. Sore throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.</p>	<p>Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:</p> <ul style="list-style-type: none"> • hives • facial swelling • asthma (wheezing) • shock <p>Sore throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.</p>
<p>Do not use if the child has ever had an allergic reaction to any other pain reliever/fever reducer</p>	<p>Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer</p>
<p>Ask a doctor before use if the child has</p> <ul style="list-style-type: none"> • not been drinking fluids • bleeding problems • lost a lot of fluid due to continued vomiting or diarrhea • problems or serious side effects from taking fever reducers or pain relievers • stomach problems that last or come back, such as heartburn, upset stomach or pain • high blood pressure, heart or kidney disease or is taking a diuretic 	<p>Ask a doctor before use if the child has</p> <ul style="list-style-type: none"> • not been drinking fluids • lost a lot of fluid due to continued vomiting or diarrhea • stomach pain • problems or serious side effects from taking fever reducers or pain relievers
<p>Ask a doctor or pharmacist before use if the child is</p> <ul style="list-style-type: none"> • under a doctor’s care for any serious medical condition • taking any other product that contains ibuprofen, or any other pain reliever/fever reducer • taking a prescription drug for anticoagulation (blood thinning) • taking any other drug 	<p>Ask a doctor or pharmacist before use if the child is</p> <ul style="list-style-type: none"> • under a doctor’s care for any serious medical condition • taking any other product that contains ibuprofen, or any other pain reliever/fever reducer • taking any other drug
<p>When using this product give with food or milk if stomach upset occurs</p>	<p>When using this product give with food or milk if stomach upset occurs</p>
<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • an allergic reaction occurs. Seek medical help right away. • fever or pain gets worse or lasts more than 3 days • stomach pain or upset gets worse or lasts • redness or swelling is present in the painful area • any new symptoms appear 	<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • an allergic reaction occurs. Seek medical help right away. • fever or pain gets worse or lasts more than 3 days • stomach pain or upset gets worse or lasts • redness or swelling is present in the painful area • any new symptoms appear

Bottle Label

See box for important information and save for future use.

Active ingredient (in each tablet)
Ibuprofen 100 mg..... Fever reducer/Pain reliever

Purposes
Ibuprofen temporarily: ■ reduces fever ■ relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

Warnings
Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:
■ hives ■ asthma (wheezing) ■ facial swelling ■ shock
Stomach bleeding warning: Taking more than recommended may cause stomach bleeding. **Sore throat warning:** Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor. Do not use if the child has ever had an allergic reaction to any other fever reducer/pain reliever. Stop use and ask a doctor if an allergic reaction occurs. Seek medical help right away.

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

Directions ■ do not give more than directed ■ find right dose on chart below. If possible, use weight to dose; otherwise use age. ■ repeat dose every 6-8 hours, if needed ■ do not use more than 4 times a day

Dosing Chart

Weight (lb)	Age (yr)	Dose (tablets)
Under 48 lb	under 5 yr	ask a doctor
48-71 lb	6-10 yr	2 tablets
72-95 lb	11 yr	3 tablets

One Dose Lasts 6-8 Hours
Store at 20-25°C (68-77°F)
Questions or comments? Call toll-free 1-800-88-ADVIL or ask your pharmacist, doctor, or health care professional

Wyeth Consumer Healthcare
Meadow, NJ 07940 Made in USA

U0175-10-N1

24 COATED TABLETS

REVIEWER'S COMMENTS

I. Carton Label: Principal Display Panel

Statement of identity

The statement of identity (established name), as printed in the submitted labeling, does not comply with 21 CFR 201.61(b) and (c). According to 21 CFR 201.61(b), the statement “shall be placed in *direct conjunction* with the most prominent display of the proprietary name or designation” (italics added for emphasis). In this case, the statement of identity is separated from the proprietary name by the phrase “Easy to Swallow Tablets.” According to 21 CFR 201.61(c), the statement of identity shall be “presented in bold face type...in a size reasonably related to the most prominent printed matter on [the] panel.” The type size of the statement of identity in this case is smaller than the type size used for the phrases “Easy to Swallow Tablets,” “Fever,” and “24 COATED TABLETS.” Therefore, the sponsor should increase the font size of the statement of identity.

The discrepancy in placement of the statement of identity (21 CFR 201.61(b)) was inadvertently overlooked in the two most recent annual reports (Y-006 and Y-007).

II. Carton Label: Drug Facts *Warnings*

Note: the sponsor did not make any changes to Drug Facts labeling other than in warnings statements.

A. Stomach bleeding warning

The sponsor has added a stomach bleeding warning: “**Stomach bleeding warning:** Taking more than recommended may cause stomach bleeding” to all carton labels.

NDAC recommended that consumers be provided with organ-specific information in the labeling of NSAIDs. The sponsor’s proposed warning includes information on the risk of stomach bleeding if the recommended dose is exceeded. This sponsor-proposed warning statement is acceptable as interim language until FDA provides guidance on specific wording based on NDAC’s recommendation.

B. Ask a doctor before use if you have

The sponsor added four bulleted statements on the carton label:

- stomach problems that last or come back, such as heartburn, upset stomach, or pain (replaces phrase “stomach pain”)
- ulcers
- bleeding problems
- high blood pressure, heart or kidney disease, or is taking a diuretic

The proposed changes are in accordance with § 343.50(c)(1)(ix)(B) as proposed in the TFM and, therefore, are acceptable.

C. Ask a doctor or pharmacist before use if you are

The sponsor made the following change:

- Added the bulleted statement “taking a prescription drug for anticoagulation (blood thinning).”

This change is in accordance with § 343.50(c)(1)(ix)(C) as proposed in the TFM and, therefore, is acceptable.

III. Bottle Label

A. The sponsor has removed the following information from the principal display panel (PDP):

- Ages 6-11
- IBUPROFEN TABLETS 100 mg

Because these statements are included on the carton PDP, their omission on the bottle PDP is acceptable.

B. The sponsor added “**Stomach bleeding warning:** Taking more than recommended may cause stomach bleeding.” This change is in accordance with NDAC recommendations (September 20, 2002) and is acceptable.

C. The sponsor revised the statement “do not give more than directed” so that it now appears in bold type. The proposed revision is acceptable.

D. The sponsor added the statement “One Dose Lasts 6-8 Hours” (bold type) below the dosing chart. The proposed revision is acceptable.

E. The sponsor added a sore throat warning as follows:

“**Sore throat warning:** Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.”

This warning is identical to the sore throat warning that appears in the Drug Facts panel and is acceptable.

RECOMMENDATIONS

1. Issue an **APPROVAL** letter to the sponsor based on final printed labeling submitted for the 24 count Junior Strength Advil tablets.
2. Advise the sponsor to make the following changes to the carton PDP at the time of next printing or 180 days whichever is sooner:
 - Place the statement of identity (Ibuprofen Tablets, 100 mg, Fever Reducer/Pain Reliever) immediately adjacent to (i.e., under) the proprietary name in accordance with 21 CFR 201.61(b).
 - Increase the font size of the statement of identity so that it is more “reasonably related to the most prominent printed matter on [the principal display] panel” in accordance with 21 CFR 201.61(c).
3. Inform the sponsor of the following:
 - FDA is concerned about the need for organ-specific warnings on OTC drug products containing analgesic/antipyretic active ingredients. The sponsor-proposed stomach bleeding warning statement is acceptable as interim language until FDA provides guidance on specific wording and placement of organ-specific warnings in the labeling of drug products containing acetaminophen and/or NSAIDs in the future. At such time, the warning may need to be revised.
 - This labeling, though recommended for approval, may not be consistent with the recently approved labeling for the same active ingredient (i.e. ibuprofen) in other NDAs and in the TFM. When the final rule is published, the labeling of these products may need to be revised in accordance with the final rule.

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

/s/

Michael Koenig
3/19/04 12:39:18 PM
INTERDISCIPLINARY

Matthew Holman
3/23/04 03:10:19 PM
INTERDISCIPLINARY

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 20-267/S-009

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**

Wyeth Consumer Healthcare
Five Giralda Farms
Madison, NJ 07940

Lauren Quinn
Associate Director, Regulatory Affairs
973-660.6167
quinnL4@wyeth.com

Wyeth

March 2, 2004

NDA NO. 20-267 REF NO. 009
NDA SUPPL FOR SIR

NDA 20-267

**Junior Strength Advil® Tablets
(Ibuprofen 100 mg)**

**Special Supplement-Changes Being Effected
(Revised Warnings)**

Charles Ganley, M.D., Director
Division of OTC Drug Products (**HFD-560**)
Center for Drug Evaluation and Research
Food and Drug Administration
ATTENTION: Document Control Room
9201 Corporate Blvd.
Rockville, MD 20850

Dear Dr. Ganley:

Reference is made to NDA 20-267 for Junior Strength Advil® Tablets sponsored by Wyeth Consumer Healthcare. Reference is also made to the Proposed Rule [FR 67 (162)] for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products, dated August 21, 2002 and the September 20, 2002 Nonprescription Drug Advisory Committee Meeting on NSAID's. Further reference is made to the ibuprofen warning changes requested in the approval letter for NDA 21-441 for Advil® Allergy Sinus Caplets. A table comparing the new/revised warnings to previous warnings for Junior Strength Advil® Tablets is included in Attachment 1.

Pursuant to 21 CFR 314.70(c), Wyeth Consumer Healthcare herein submits 12 copies of the updated final printed labeling in the form of a Special Supplement-Changes Being Effected. The following labeling components are enclosed:

Junior Strength Advil® 24 Coated Tablets (Carton & Bottle)

If you have any questions regarding this information, please contact the undersigned at (973) 660-6167 or Dr. David Smith at (973) 660-6806.

Regards,
WYETH CONSUMER HEALTHCARE

Lauren Quinn

Lauren Quinn
Associate Director, Regulatory Affairs

RECEIVED

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NAI 3/22/04
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