Approval Package for:

APPLICATION NUMBER: NDA 19-872/S-029

Name: Tylenol 8-Hour (650 mg acetaminophen) Extended-release Tablets and Tylenol Arthritis Pain (650 mg acetaminophen) Extended-release Tablets

Sponsor: McNeil Consumer Healthcare

Approval Date: February 28, 2008

APPLICATION NUMBER: NDA 19-872/S-029

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APPLICATION NUMBER: NDA 19-872/S-029

APPROVAL LETTER



Public Health Service

Food and Drug Administration Rockville, MD 20857

NDA 19-872/S-029

McNeil Consumer Healthcare
Attention: Victoria Wagner-Weber
Director, Global Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Wagner-Weber:

Please refer to your supplemental new drug application dated August 30, 2007, received August 31, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tylenol 8-Hour (650 mg acetaminophen) extended-release tablets and Tylenol Arthritis Pain (650 mg acetaminophen) extended-release tablets.

We acknowledge receipt of your submissions dated October 12, and December 6, 2007, and January 4, 25, and 28, and February 15, 2008.

This "Changes Being Effected" supplemental new drug application provides for revisions to the principal display panel (PDP) and Drug Facts label for Tylenol Arthritis Pain extended-release gelatin-coated tablets (geltabs) in response to the July 31, 2007 supplement request letter.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the Tylenol Arthritis Pain geltabs 20-, 40-, and 80-count immediate container and carton labels submitted on February 15, 2008.

We remind you of your postmarketing study commitment in your submission dated January 28, 2008. This commitment is listed below.

1. Reformulate the Tylenol Arthritis Pain extended-release geltabs and submit the appropriate data to support improved swallowability of this medication.

Final Report Submission: by June 2009

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Commitment Protocol", "Postmarketing Study Commitment Final Report", or "Postmarketing Study Commitment Correspondence."

NDA 19-872/S-029 Page 2

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 Food and Drug Administration 5515 Security Lane HFD-001, Suite 5100 Rockville, MD 20852

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 Neel Patel, Regulatory Project Manager, at 301-796-0970.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

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/s/

Joel Schiffenbauer

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APPLICATION NUMBER: NDA 19-872/S-029

LABELING

NOTES:

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2) ALL DIMENSIONS IN INCHES

3) TOLERANCES UNLESS SPECIFIED:
FRACTIONS 1/32
ANGLES 11*

4) --- NO PRINT

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6) WW UPC AREA (NO COLOR)

7) GLUE AREA (NO COPY, NO COLOR, NO VARNISH)

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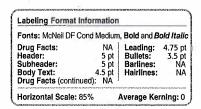
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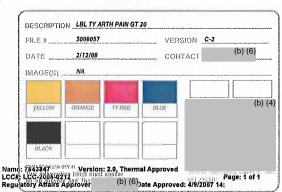


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NOTES:

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- 2) ALL DIMENSIONS IN INCHES
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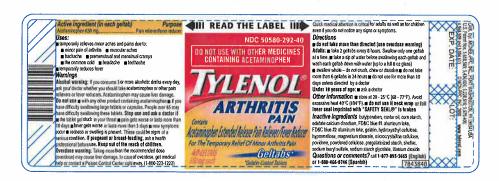
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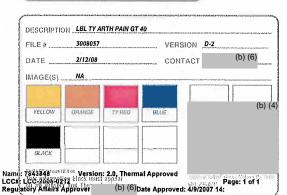


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2) ALL DIMENSIONS IN INCHES
3) TOLERANCES UNLESS SPECIFIED;
FRACTIONS ±1/32
ANGLES ±1*
4) ---- NO PRINT

5) LOT AREA
6) EXP. DATE AREA

7) WW UPC AREA

8) NO VARNISH AREA

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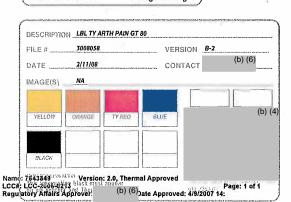
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APPLICATION NUMBER: NDA 19-872/S-029

LABELING REVIEWS



OTC Drug Labeling Review for Tylenol® Arthritis Pain Geltabs

Office of Nonprescription Products

Center for Drug Evaluation and Research • Food and Drug Administration

SUBMISSION DATE: August 30, 2007 **RECEIVED DATE:** August 31, 2007

REVIEW DATE: September 24, 2007

NDA/SUBMISSION TYPE: NDA 19-872/SLR-029

SPONSOR/CONTACT: McNeil Consumer & Specialty

Pharmaceuticals 7050 Camp Hill Road

Fort Washington, PA 19034-2299

Victoria M. Wagner-Weber

Director, Global Regulatory Affairs

215-273-8278

FAX: 215-273-4123

DRUG PRODUCT: Tylenol Arthritis Pain Geltabs

ACTIVE INGREDIENT: Acetaminophen, 650 mg

INDICATIONS: Pain reliever

PHARMACOLOGICAL CATEGORY: Internal analgesic

LABELING SUBMITTED: 20-, 40-, and 80-count containers and outer

cartons

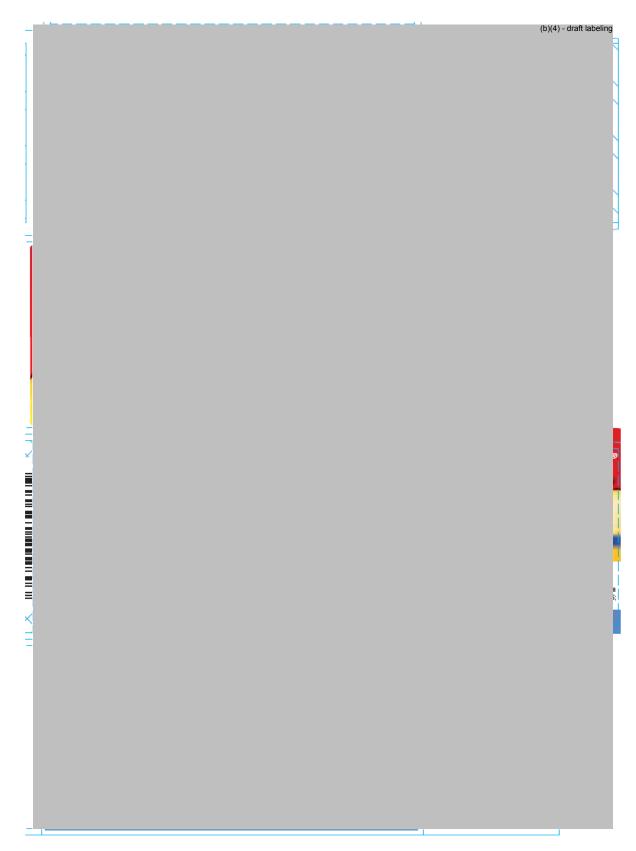
REVIEWER: Michael L. Koenig, Ph.D.

TEAM LEADER: Matthew R. Holman, Ph.D.

BACKGROUND

Because we had safety concerns regarding the use of gel-coated extended release Tylenol products, FDA requested that the sponsor submit postmarketing safety information on choking and esophageal impaction for these dosage forms. The sponsor submitted a tabulation of all adverse events associated with the use of gel-coated and other solid-dose Tylenol products on November 16, 2006, and January 12, 2007. We reviewed these data and requested that the sponsor meet with us to discuss our concerns. The sponsor met with us on May 22, 2007, and submitted proposed revised labeling for Tylenol Arthritis Pain geltabs on May 25, 2007. We reviewed that labeling based on the last approved labeling (SCP-021, approved on November 3, 2004) and requested CBE supplemental labeling on July 31, 2007. The sponsor submitted this supplement (SLR-029) on August 31, 2007, and indicated that they intended to implement these changes at the time of next printing but no later than January 30, 2008.

REPRESENTATIVE CARTON LABEL



REPRESENTATIVE CONTAINER LABEL

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REVIEWER'S COMMENTS

- 1. The sponsor made all of the changes requested in our August 31, 2007, supplemental labeling request letter:
 - Added the statement "See New Warnings and Directions" to the principal display panels on the carton and container
 - Added as the second statement under the Warnings "Do not use" subheading, "if you have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets."
 - Added the bulleted statement under Warnings "Stop use and ask a doctor if" subheading, "the tablet got stuck in your throat"
 - Under the Directions heading, revised the bulleted statement "take 2 geltabs every 8 hours with water" to read, "take 2 geltabs every 8 hours. Swallow only one geltab at a time."
 - Added, as the second bulleted statement under Directions, "take a sip of water before swallowing each geltab and wash each geltab down with water (up to a full 8 oz. glass)"

These changes are acceptable.

2. The active ingredient in this product, acetaminophen, is indicated for both pain relief and fever reduction (proposed 21 CFR 343.50(b), 53 FR 46204 at 46255). However, the sponsor is using only the "pain reliever" indication. We agreed to the the listing of "pain reliever" as the sole indication when the sponsor proposed arthritis pain relief as the sole intended use of this product (SLR-009 Labeling Review, July 17, 2000). In light of new evidence that excessive acetaminophen can result in hepatotoxicity (71 FR 77314), we now have serious safety concerns about not including both indications. We believe it is misleading to exclude the "fever reducer" indication. In the absence of this indication, consumers may unintentionally take this product for (arthritis) pain relief and an alternative acetaminophen-

containing analysesic product to reduce the effects of a concurrent fever. This concurrent use of multiple acetaminophen products could lead to serious, if not fatal, hepatotoxicity.

This reviewer believes the sponsor should list all indications and warnings appropriate to acetaminophen as both a pain reliever and fever reducer. Accordingly, we should require the sponsor to:

- Revise the statement of identity on the principal display panels (PDPs) of both the carton and container to identify the general pharmacological category as "pain reliever/fever reducer".
- Revise the general pharmacological category under the *Purpose* heading to read, "pain reliever/fever reducer".
- Add the indication "temporarily reduces fever" under the *Uses* heading.

This reviewer notes that the sponsor already includes the bulleted statement "fever gets worse or lasts more than 3 days" under the Warnings "Stop use and ask a doctor if" subheading.

RECOMMENDATIONS

Issue a discipline review letter to the sponsor requesting revised labeling with the following required changes to the carton and container labels for Tylenol Arthritis Pain geltabs:

- Revise the statement of identity on the principal display panels (PDPs) of both the carton and container to identify the general pharmacological category as "pain reliever/fever reducer".
- Revise the general pharmacological category under the *Purpose* heading to read, "pain reliever/fever reducer".
- Add the indication "temporarily reduces fever" under the *Uses* heading.

These revisions are required to prevent consumer confusion, which may lead to serious or fatal hepatotoxicity. Without these revisions, consumers may simultaneously take this product for relief of arthritis pain and take another acetaminophen product for fever reduction. This could result in acetaminophen-induced hepatotoxicity, as discussed in the December 2006 internal analgesic proposed rule (71 FR 77314). Including all of the indications and warnings minimizes this safety risk.

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/s/

Michael Koenig 9/24/2007 09:12:28 AM

INTERDISCIPLINARY

Matthew Holman 9/24/2007 09:22:27 AM INTERDISCIPLINARY



OTC Drug Labeling Review for Tylenol® Arthritis Pain Geltabs (FPL)

Office of Nonprescription Products

Center for Drug Evaluation and Research • Food and Drug Administration

SUBMISSION DATE: December 6, 2007

January 4, 2008 February 15, 2008 **RECEIVED DATE:** December 7, 2007

January 5, 2008 February 19, 2008

REVIEW DATE: February 22, 2008

NDA/SUBMISSION TYPE: NDA 19-872/SLR-029/FA

SPONSOR/CONTACT: McNeil Consumer & Specialty

Pharmaceuticals 7050 Camp Hill Road

Fort Washington, PA 19034-2299

Victoria M. Wagner-Weber

Director, Global Regulatory Affairs

215-273-8278

FAX: 215-273-4123

DRUG PRODUCT: Tylenol Arthritis Pain Geltabs

ACTIVE INGREDIENT: Acetaminophen, 650 mg

INDICATIONS: Pain reliever/fever reducer

PHARMACOLOGICAL CATEGORY: Internal analgesic

LABELING SUBMITTED: 20-, 40-, and 80-count containers and outer

cartons

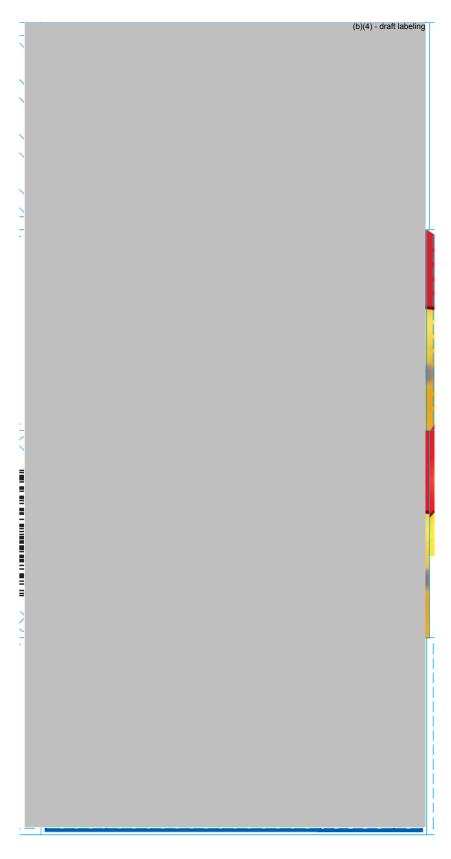
REVIEWER: Michael L. Koenig, Ph.D.

TEAM LEADER: Matthew R. Holman, Ph.D.

BACKGROUND

The sponsor submitted proposed revised labeling for Tylenol Arthritis Pain geltabs on May 25, 2007. We reviewed that labeling based on the last approved labeling (SCP-021, approved on November 3, 2004) and requested CBE supplemental labeling on July 31, 2007. The sponsor submitted this supplement (SLR-029) on August 31, 2007, and indicated that they intended to implement these changes at the time of next printing but no later than January 30, 2008. We issued a discipline review letter on October 2, 2007, specifying that changes needed to be made to the both the Principal Display Panel and Drug Facts Panel. The sponsor revised the labeling and submitted final printed labeling (FPL) on December 6, 2007. We requested two additional changes to the labeling in an e-mail message dated December 17, 2007. The sponsor replied to our request in a letter dated January 4, 2008 and submitted revised FPL on February 15, 2008.

REPRESENTATIVE CARTON LABEL



REPRESENTATIVE CONTAINER LABEL



REVIEWER'S COMMENTS

- 1. The sponsor made the changes requested in our October 2, 2007, discipline review letter:
 - Revised the statement of identity on the principal display panel (PDP) on the container and outer carton to identify the general pharmacological category as "Pain reliever/fever reducer."
 - Revised the general pharmacological category under the heading "Purpose" (Drug Facts panel) to read "pain reliever/fever reducer")
 - Added the indication "temporarily reduces fever" under the heading "Uses" (Drug Facts panel).
- 2. We informed the sponsor that the general pharmacological category included in the statement of identity on the PDP does not meet the requirements in § 201.61(c). The general pharmacological category is <u>not</u> in a "size reasonably related to the most prominent printed matter" on the PDP. We advised the sponsor to increase the size of the text used to describe the general pharmacological category, so that it is at least as large as the other text in the statement of identity ("Acetaminophen Extended Release Pain Reliever"). The size of the text has been increased in the revised labeling received on February 19, 2008. This is acceptable.
- 3. We also informed the sponsor that the minimum age specified in the *Directions* for both the Arthritis Pain Relief and 8-Hour products should be the same. The 8-Hour product specifies that persons under 12 years of age should ask a doctor before using that product. The Arthritis Pain Relief product specifies that anyone under 18 years of age should ask a doctor before using that product. We advised the sponsor to use a common minimum age of 12 years on both products.

On January 4, 2008, the sponsor requested that it not be required to change the minimum age for Tylenol Arthritis Pain to 12 years of age. The sponsor provided a copy of an action letter dated April 13, 2000, in which we specifically requested that the directions specify a minimum age of 18 years. In the action letter, we expressed concern about the potential confusion a product name emphasizing arthritis (and not the other indications for which acetaminophen is used) might engender. Upon further review, we agree with the sponsor and are not requiring that a minimum of age of 12 years be specified on both the Tylenol 8-Hour and Tylenol Arthritis Pain products.

RECOMMENDATION

Issue an APPROVAL letter to the sponsor. The final printed labeling submitted on February 15, 2008 for the 20-, 40-, and 80-count containers and outer cartons of Tylenol® Arthritis Pain Geltabs is approved.

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/s/

Michael Koenig

2/24/2008 02:03:09 PM INTERDISCIPLINARY

Matthew Holman 2/25/2008 08:02:02 AM INTERDISCIPLINARY

NDA 19-872/S-029

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

Food and Drug Administration Rockville, MD 20857

SUPPLEMENTAL LABELING REQUEST - CBE

NDA 19-872

McNeil Consumer Healthcare
Attention: Victoria Wagner-Weber
Director, Global Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Wagner-Weber:

Please refer to your new drug application (NDA) approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tylenol 8 Hour (650 mg acetaminophen) extended release tablets.

We additionally refer to the meeting between representatives of your firm and FDA on May 22, 2007, to discuss the adverse event reports of choking and esophageal impaction involving the use of Tylenol[®] Arthritis Pain Extended Release geltabs and Tylenol[®] 8 Hour Extended Release geltabs. FDA issued the official meeting minutes on June 5, 2007.

We also refer to your correspondence dated May 25, 2007, containing a proposed action plan with labeling revisions to address FDA's safety concerns with use of this product. We agree that labeling changes are warranted to include more specific information for consumers about the potential for swallowing difficulties. Therefore, we request that you revise the most recently approved labeling for Tylenol[®] Arthritis Pain Extended Release geltabs and Tylenol[®] 8 Hour Extended Release geltabs, as follows:

1. Principal Display Panel (PDP)

Add the statement "See New Warnings and Directions". This statement should be highlighted in either fluorescent or color contrast or be printed in bold type, and the size should be at least one-third the size of the most prominent printed matter on the PDP. This statement will be required to remain on the PDP until the safety issue is adequately resolved.

2. Drug Facts Panel (Carton)

a. Under the Warnings "Do not use" subheading, add as the second bulleted statement "if you have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets."

Page 2

- b. Under the Warnings "Stop use and ask a doctor if" subheading, add the bulleted statement "the tablet got stuck in your throat".
- c. Under the Directions heading:
 - i. Revise the bulleted statement "take 2 geltabs every 8 hours with water" to read "take 2 geltabs every 8 hours. Swallow only one geltab at a time."
 - ii. Add as the second bulleted statement "take a sip of water before swallowing each geltab and wash each geltab down with water (up to a full 8 oz glass)".

In addition to the above recommended language, the Drug Facts label must be formatted in accordance with the requirements of 21 CFR 201.66.

These labeling revisions should be submitted to FDA in the form of a "Supplement – Changes Being Effected" within 30 days from the date of this letter in accordance with the requirements of 21 CFR 314.70. Color-mock up labeling can be submitted in lieu of final printed labeling.

These labeling changes should be implemented at the time of next printing or 180 days, whichever comes first. If you are unable to meet this deadline, contact us to discuss the timing of the new labeling.

In addition, we have the following comments related to your May 25, 2007 submission containing your proposed action plan intended to address the choking and esophageal impaction adverse events associated with the use of Tylenol[®] Arthritis Pain Extended Release geltabs and Tylenol[®] 8 Hour Extended Release geltabs:

- 1. You should initiate your proposed enhanced monitoring and improved customer call center. However, we recommend that the additional information obtained from the consumer in your proposed enhanced monitoring plan include details of how the event developed (e.g. number of tablets attempted at one time, with or without liquid, whether subject was sitting or lying down, concurrent conditions and treatments, prior medical history of difficulty swallowing) and the outcome of the event. The quarterly reports should include all AEs, regardless of outcome.
- 2. You should reformulate the Tylenol[®] Arthritis Pain Extended Release geltabs (650 mg) and 8 Hour Extended Release geltabs (650 mg) to improve the ability of consumers to swallow these medications. In a future communication, we will discuss the details of (and your commitment to) this reformulation.

If you have any questions, call Neel Patel, Regulatory Project Manager, at 301-796-0970.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

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/s/

Andrea Segal

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Food and Drug Administration

Center for Drug Evaluation and Research NO.19-672 REFNO. 039

Division of Nonprescription Clinical Evaluation SUPPL FOR _

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5901-B Ammendale Road

Beltsville, MD 20705-1266

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RE:

NDA 19-872

Tylenol® 8-Hour (650 mg acetaminophen) extended-release tablets

Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release tablets

Supplement - Changes Being Effected with Draft Printed Labeling

Dear Dr. Leonard-Segal:

Please refer to FDA's July 31, 2007 Supplemental Labeling Request – CBE (Attachment 1) received by McNeil Consumer Healthcare ("McNeil") on August 1, 2007 regarding labeling changes for the above referenced New Drug Application (NDA) approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act.

This submission provides draft printed labeling for Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release tablets (20-, 40-, and 80-count package sizes) (Attachment 2) as requested by the Division in its July 31, 2007 correspondence. In addition, a CD-ROM containing the electronic copies of these draft printed labels is included in both the Archive and Review copies of this submission. The files were scanned with McAfee VirusScan Enterprise, Version 8.0.0, Virus Definitions 4783, Scan Engine 4400 and are virus free.

Specifically, the draft printed labeling for Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release tablets has been revised as follows:

1. Principal Display Panel (PDP)

The statement "See New Warnings and Directions" is added to the primary PDP of the carton and to the PDP of the bottle label. This statement is printed in bold type and its size is one-third the size of the most prominent printed matter on the primary PDP of the carton. McNeil commits to maintain this statement on the PDP until the safety issue is adequately resolved.

2. Drug Facts Panel (Carton)

The Drug Facts label of the carton is revised to incorporate the language recommended in FDA's July 31, 2007 Supplemental Labeling Request - CBE and is formatted in accordance with the requirements of 21 CFR 201.66:

- a. Under the Warnings "Do not use" subheading, the statement "if you have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets." is added as the second bullet.
- b. Under the Warnings "Stop use and ask a doctor if" subheading, the statement "the tablet got stuck in your throat." is added as the first bullet.
- c. Under the Directions heading:
 - The first bulleted statement "take 2 geltabs every 8 hours with water." is revised to read, "take 2 geltabs every 8 hours. Swallow only one geltab at a time."
 - The statement "take a sip of water before swallowing each geltab and wash each geltab down with water (up to a full 8 oz. Glass)" is added as the second bullet.

3. Bottle Label

To maintain consistency, the bottle label is also revised to contain the same language as the Drug Facts label of the carton.

McNeil commits to implement the revised printed labeling at the time of next printing but no later than January 30, 2008. Final Printed Labeling (FPL) will be submitted in accordance with 21 CFR 314.70(c)(6).

As reported in the most recent Annual Report for this NDA, Tylenol® 8-Hour (650 mg acetaminophen) extended-release tablets has been discontinued. Should McNeil decide to re-introduce Tylenol® 8-Hour (650 mg acetaminophen) extended-release tablets in the future, the labeling for this product will be revised and submitted in accordance with FDA's July 31, 2007 Supplemental Labeling Request – CBE.

Please contact me if you have any questions or require additional information, at 215-273-8278 or in my absence, Lynn Pawelski, Vice President, Regulatory Affairs at 215-273-7731.

Sincerely,

MCNEIL CONSUMER HEALTHCARE

Victoria M. Wagner-Weber

Director, Global Regulatory Affairs

cc: Neel Patel, Regulatory Project Manager

1. Stagnu- Hele



Public Health Service

Food and Drug Administration Rockville, MD 20857

NDA 19-872/S-029

CBE-0 SUPPLEMENT

McNeil Consumer Healthcare
Attention: Victoria Wagner-Weber
Director, Global Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Wagner-Weber:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Tylenol® 8-Hour (650 mg acetaminophen) extended-release

tablets

Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-

release tablets

NDA Number: 19-872

Supplement number: 029

Date of supplement: August 30, 2007

Date of receipt: August 31, 2007

This supplemental application, submitted as "Supplement - Changes Being Effected" provides for revisions to the principal display panel (PDP) and Drug Facts label for Tylenol® Arthritis Pain in response to the July 31, 2007 supplement request letter.

According to your submission, Tylenol 8-Hour has been discontinued. Therefore, no labeling changes for this trade name have been submitted.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on October 30, 2007, in accordance with 21 CFR 314.101(a). If the application is filed, the goal date will be February 29, 2008.

Please cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

NDA 19-872/S-029 Page 2

> Food and Drug Administration Center for Drug Evaluation and Research Office of Nonprescription Products Division of Nonprescription Clinical Evaluation 5901-B Ammendale Road Beltsville, MD 20705-1266

If you have any questions, call Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Leah Christl, Ph.D.
Chief, Project Management Staff
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

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/s/

Table Classical I

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Food and Drug Administration Rockville, MD 20857

NDA 19-872/S-029

DISCIPLINE REVIEW LETTER

McNeil Consumer Healthcare
Attention: Victoria Wagner-Weber
Director, Global Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Wagner-Weber:

Please refer to your August 30, 2007 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tylenol 8 Hour (650 mg acetaminophen) extended release tablets.

Our review of the labeling in your submission is complete, and we have identified the following deficiency:

We are concerned that consumers may simultaneously take your product for relief of arthritis pain and another acetaminophen product for fever reduction. This could result in serious or fatal acetaminophen-induced hepatotoxicity. To prevent consumer confusion and a potential overdose of acetaminophen, you must revise the labeling for Tylenol[®] Arthritis Pain extended release tablets, as follows:

1. Principal Display Panel (PDP)

Revise the statement of identity to identify the general pharmacological category as "pain reliever/fever reducer".

- 2. Drug Facts Panel (Carton and Immediate Container)
 - a. Under the heading "Purpose", revise the general pharmacological category to read, "pain reliever/fever reducer".
 - b. Under the heading "Uses", add the indication "temporarily reduces fever".

According to your submission, Tylenol 8-Hour has been discontinued. Therefore, no labeling changes for this trade name have been submitted.

NDA 19-872/S029 Page 2

We are providing these comments to give you <u>preliminary</u> notice of issues that we have identified. In conformance with the prescription drug user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and subject to change as we finalize our review of your application. In addition, we may identify other information that must be provided before we can approve this application. If you respond to these issues during this review cycle, depending on the timing of your response, and in conformance with the user fee reauthorization agreements, we may not be able to consider your response before we take an action on your application during this review cycle.

In order to ensure a timely action for this new drug application, we request that you respond to the issues listed above as soon as possible and submit new, revised labeling with these changes as an amendment to your August 30, 2007 labeling supplement.

Please cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration Center for Drug Evaluation and Research Office of Nonprescription Products Division of Nonprescription Clinical Evaluation 5901-B Ammendale Road Beltsville, MD 20705-1266

If you have any questions you may contact Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD Director Division of Nonprescription Clinical Evaluation Office of Nonprescription Products Center for Drug Evaluation and Research

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this page is the manifestation of the electronic signature.	

/s/

Andrea Segal

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Andrea Leonard-Segal, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Nonprescription Products (HFD-560)
Division of Nonprescription Clinical Evaluation

Document Control Room 5901-B Ammendale Road Beltsville, MD 20705-1266 SUPPL NEW CORRESP

OCT 1 5 2007

CDER CDR

OCT 172007

RE:

NDA 19-872/S029

Tylenol® 8-Hour (650 mg acetaminophen) extended-release tablets

Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release tablets

Response to Discipline Review Letter: Label Changes

Dear Dr. Leonard-Segal:

Please refer to the August 30,2007 supplemental new drug application submitted under section 505(b)2 of the Federal Food, Drug, and Cosmetic Act for Tylenol® 8-Hour (650 mg acetaminophen) extended-release tablets implementing label changes to address the swallowability of Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release geltabs. These changes were agreed to during a meeting held between FDA and McNeil Consumer Healthcare ("McNeil") on May 22, 2007. Please refer also to the October 2, 2007 Discipline Review Letter (DRL) received by McNeil commenting on those label changes. McNeil commits to making the requested changes to the Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release geltabs and caplet products.

At this time McNeil wants to clarify a statement in the DRL noting that the Tylenol® 8-Hour product has been discontinued and therefore no labeling changes are needed. Indeed, the Tylenol® 8-Hour (650 mg acetaminophen) extended-release geltabs have been discontinued, as reported in the most recent annual report for the referenced NDA. However, the Tylenol 8-Hour (650 mg acetaminophen) extended-release caplets have not been discontinued. Furthermore, "fever reducer" is already on the Principal Display Panel and the Drug Facts of the 8-Hour caplets.

Products currently marketed under NDA 19-872 are the following:

- Tylenol® 8-Hour (650 mg acetaminophen) extended-release caplets
- Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release caplets
- Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release geltabs

The data and information contained in this submission constitute trade secrets and confidential commercial information (see 21 C.F.R. 20.61). McNeil Consumer Healthcare, a division of McNEIL-PPC, Inc hereby claims the legal protections afforded such trade secret and confidential information under 5.U.S.C. 552(b), 21 U.S.C. 331(j) and 18 U.S.C. 1905. Further dissemination may only be made with the express written permission of McNeil Consumer Healthcare, a division of McNEIL-PPC, Inc.

Please contact me if you have any questions or require additional information, at 215-273-8278 or in my absence, Lynn Pawelski, Vice President, Regulatory Affairs at 215-273-7731.

Sincerely,

MCNEIL CONSUMER HEALTHCARE

Victoria M. Wagner-Weber

Director, Global Regulatory Affairs

cc: Neel Patel, Regulatory Project Manager

The data and information contained in this submission constitute trade secrets and confidential commercial information (see 21 C.F.R. 20.61). McNeil Consumer Healthcare, a division of McNEIL-PPC, Inc hereby claims the legal protections afforded such trade secret and confidential information under 5.U.S.C. 552(b), 21 U.S.C. 331(j) and 18 U.S.C. 1905. Further dissemination may only be made with the express written permission of McNeil Consumer Healthcare, a division of McNEIL-PPC, Inc.





Andrea Leonard-Segal, M.D.

Acting Director, Division of Nonprescription Clinical Evaluation

Office of Nonprescription Products (HFD-560)

Center for Drug Evaluation and Research

Document Control Room

5901-B Ammendale Road

Beltsville, MD 20705-1266

CDER/CDR

DEC 0 7 2007

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ORIGINAL

RE:

NDA 19-872/029

Tylenol 8-Hour (650 mg acetaminophen) extended-release tablets Tylenol Arthritis Pain Relief (650 mg acetaminophen) extended-release tablets Final Printed Labeling (FPL)

Dear Dr. Leonard-Segal:

SLR 029-13F NDA SUPPL AMENDMENT

Please refer to the NDA 19-872/S-029 submitted under section 505 (b) 1 of the Federal Food Drug and Cosmetic Act for Tylenol[®] 8-Hour (650 mg acetaminophen) extended-release tablets and Tylenol[®] Arthritis Pain Relief (650 mg acetaminophen) extendedrelease tablets. Supplement 029 delineates label changes to address swallowability issues associated with Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extendedrelease geltabs ("TAR geltabs"). These label changes were discussed during a meeting held between FDA and McNeil Consumer Healthcare ("McNeil") on May 22, 2007. Please refer to FDA's July 31, 2007 supplemental labeling request for the TAR geltab product, to McNeil's August 30, 2007 submission of draft labeling, and to the October 2, 2007 Discipline Review Letter ("DRL"). All requested revisions have now been incorporated into the new labels for the 20-, 40- and 80-count package sizes of Tylenol Arthritis Pain extended-release geltabs.

At this time, McNeil is submitting the FPL electronically, in accordance with the Guidance for Industry, Providing Regulatory Submissions in Electronic Format - NDAs (January 1999). A CD-ROM is included in both the Archive and Review copies of this submission. The files were scanned with McAffee Virus Scan Enterprise, Version 8.0.0, Virus Definitions 4783, Scan Engine 4400 and are virus free.

Specifically, the labeling for Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release geltabs has been revised as follows:

- 1. Principal Display Panel (PDP)
 - The statement "See New Warnings and Directions" is added to the primary PDP of the carton and to the PDP of the bottle label. This statement is printed in bold type and its size is one-third the size of the most prominent printed matter on the primary PDP of the carton. McNeil commits to maintaining this statement on the PDP until the swallowability issue is adequately resolved.

The data and information contained in this submission constitute trade secrets and confidential commercial information (see 21 C.F.R. 20.61). McNeil Consumer Healthcare, a division of McNEIL-PPC, Inc hereby claims the legal protections afforded such trade secret and confidential information under 5.U.S.C. 552(b), 21 U.S.C. 331(i) and 18 U.S.C. 1905. Further dissemination may only be made with the express written permission of McNeil Consumer Healthcare, a division of McNEIL-PPC, Inc.

• Per October 2, 2007 DRL, "fever reducer" has been added to the statement of identify (SOI).

2. Drug Facts Panel (Carton)

- Under "Purpose", "fever reducer" has been added to "pain reliever"
- Under "Uses", "temporarily reduces fever" has been added
- Under "Warnings" "Do not use" subheading, the statement "if you have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets." is added as the second bullet.
- Under "Warnings" "Stop use and ask a doctor if" subheading, the statement "the tablet got stuck in your throat" is added as the first bullet.
- Under "Directions":
 - The first bulleted statement "take 2 geltabs every 8 hours with water." is revised to read "take 2 geltabs every 8 hours. Swallow only one geltab at a time."
 - The statement "take a sip of water before swallowing each geltab and wash each geltab down with water (up to a full 8 oz. glass)" is added as the second bullet.

3. Bottle Label

 To maintain consistency, the bottle label is also revised to include in the same language as the Drug Facts label on the carton.

McNeil commits to implementing the revised labeling no later than January 30, 2008.

As reported in the most recent Annual Report for this NDA, Tylenol® 8-Hour (650 mg acetaminophen) extended-release geltabs have been discontinued. Should McNeil decide to re-introduce Tylenol® 8-Hour (650 mg acetaminophen) extended-release geltabs in the future, the labeling will be revised with these same changes prior to re-introduction.

If you have any questions, please contact me at 215-273-8278 (fax: 215-273-4123).

Sincerely,

MCNEIL CONSUMER HEALTHCARE

Victoria M. Wagner-Weber

Director, Global Regulatory Affairs

Cc (Desk Copy): Neel Patel, Pharm.D, Project Manager (HFD-560)



Consumer Healthcare

JAN 0 4 2008

Andrea Leonard-Segal, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Nonprescription Products
Division of Nonprescription Clinical Evaluation
Document Control Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

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NDA SUPPL AMENDMENT SLR-029-BL

RE:

NDA 19-872/S-029

Tylenol® 8-Hour (650 mg acetaminophen) extended-release tablets

Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release tablets

Response to Request for Revisions to Labeling

Dear Dr. Leonard-Segal:

Please refer to NDA 19-827, S-029 and to Final Printed Labeling (FPL) submitted to FDA on December 6, 2007 for Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release geltabs. This letter is in reference to the subsequent request of Dr. Neel Patel, Regulatory Project Manager, on December 17, 2007, to increase the size of the text used to describe the general pharmacological category (Pain reliever/Fever reducer) and to revise the minimal age specified in the *Directions* for both the Tylenol Arthritis Pain Relief and 8-Hour formulations to include the minimum age of 12 years on both products. As indicated in Dr. Patel's request, the Tylenol® 8-Hour (650 mg acetaminophen) extended-release tablets label specifies that persons under 12 years of age should ask a doctor before using that product and the Arthritis Pain Relief label specifies that anyone under 18 years of age should ask a doctor before using that product.

Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release tablets supplement 009 was submitted on December 9, 1998 and approved on July 25, 2000. In the action letter dated April 13, 2000 (Attachment 1), Dr. Charles Ganley, Director, Division of Over-the-Counter Drug Products, specifically requested that the directions for "Tylenol Arthritis Pain" specify that children under 18 years of age should ask a doctor before use. Dr. Ganley wrote:

While this [dosing directions for children over 12 year of age] may be appropriate for the other conditions listed in the Uses section of the label, it raises concerns for this product because the product name emphasizes arthritis. The treatment of arthritis in children over 12 years of age should be diagnosed and managed by

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Response to Request for Revisions to minimal age in Directions Page 2

a physician. The Division has made this distinction in the past for treatment of other diseases in children that require a physician's recommendation before use. Most recently, your Motrin Migraine Pain product was approved with Directions instructing consumers under 18 years of age to ask a doctor before using. It would be inappropriate to suggest to the consumer that the treatment of arthritis in children over 12 years of age can be treated without first getting the advice of a doctor.

McNeil reached resolution with FDA on this issue and subsequently the Tylenol Arthritis Pain sNDA was approved by FDA effective July 25, 2000, with the directions for use changed to "under 18 years of age ask a doctor" (Attachment 2), Directions for the Tylenol 8-hour product remained at age 12 or over. Please see FPL submitted on August 31, 2000 and FDA's subsequent approval letter of the FPL dated February 28, 2001 (Attachment 3).

Consequently, McNeil is requesting that the labeling for the products referenced in Dr. Patel's request be kept consistent with the currently approved age cut-offs. That is, the Tylenol Arthritis Pain label specifying that anyone under 18 years of age should ask a doctor before using the product and Tylenol® 8-Hour (650 mg acetaminophen) extended-release tablets label specifying that anyone under 12 years of age should ask a doctor before using that product.

Regarding the size of the general pharmacological category, McNeil will increase the size of "Pain reliever/fever reducer" on the front panel.

Please contact me at 215-273-8278 if you have any questions. In the event that you are unable to reach me, please contact Lynn Pawelski, Vice President, Regulatory Affairs at 215-273-7731 or by fax at 215-273-4123.

Sincerely,

McNeil Consumer Healthcare

Victoria M. Wagner-Weber

Director, Global Regulatory Affairs

1. Stagnu-Stille

Cc: Neel Patel, PharmD., Regulatory Project Manager

Patel, Neel (CDER)

From: Patel, Neel (CDER)

Sent: Thursday, January 24, 2008 12:28 PM

To: 'Wagner-Weber, Vicki [MCCUS]'

Subject: NDA 19-872 Tylenol Arthritis Pain Extended Release geltabs

Hello Vicki,

Please refer to your new drug application (NDA) approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tylenol 8 Hour (650 mg acetaminophen) extended release tablets.

We additionally refer to the meeting between representative of your firm and the FDA on May 22, 2007 to discuss the adverse event reports of choking and esophageal impaction involving the use of Tylenol® Arthritis Pain Extended Release geltabs and 8 Hour Extended Release geltabs and the FDA supplemental labeling request letter dated July 31, 2007.

We also refer to your correspondence dated January 14, 2008 containing a status update on your swallowability improvement program and commitments made in May 2007. We have completed our review of your submission and have the comments:

- 1. We agree with your changes in post-marketing safety data collection and will review the safety update reports as they are submitted.
- 2. We do not have comments on your Educational Campaign.
- We agree with the proposed timeline for reformulation of the Tylenol Arthritis Pain Relief Geltabs.

 (b) (4)
- 4.

Per our phone conversation, we would like you to submit a letter to agree to a voluntary post marketing commitment for the reformulation timeline submitted in your January 14, 2008 correspondence as a condition of approval for S-029.

As always, feel free to call me if you have any questions.

Thanks Neel

Neel Patel. PharmD. Regulatory Project Manager Division of Nonprescription Evaluation Office of Nonprescription Products

Tel: 301-796-0970

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/s/

Nool Datol

Neel Patel 1/24/2008 01:20:52 PM

CSO



UKIGINAL

SLR-029-C SUPPL NEW CORRESP

Andrea Leonard-Segal, MD, Director Food and Drug Administration Center for Drug Evaluation and Research Office of Nonprescription Products (HFD-560) Division of Nonprescription Clinical Evaluation Document Control Room 5901-B Ammendale Road Beltsville, MD 20705-1266

RECEIVE DAN 2 5 2008

JAN 28 2008

CDER CDR

RE:

NDA 19-872/S-029

Tylenol® 8-Hour (650 mg acetaminophen) extended-release tablets
Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release tablets
Geltabs Swallowability Improvement Program: Quarterly Safety Report
Trend Analysis of Postmarketing Events Suggestive of Swallowing
Difficulty Reported With the Use of Tylenol® (acetaminophen) Arthritis
Pain Extended Release Geltab Formulation

Dear Dr. Leonard-Segal:

Please refer to the meeting held between FDA and McNeil Consumer Healthcare ("McNeil") on May 22, 2007 and to McNeil's May 25, 2007 correspondence to FDA containing McNeil's action plan to address the swallowability of Tylenol® Arthritis Pain Relief "TAR" Geltabs. As part of this action plan, McNeil agreed to provide quarterly evaluations of rates of events suggestive of swallowing difficulty based on post-marketing safety data. On September 24, 2007, McNeil submitted a report entitled "Trend Analysis of Post-marketing Events Suggestive of Swallowing Difficulty Reported With the Use of Tylenol® (acetaminophen) Arthritis Pain and 8-Hour Extended Release Geltab Formulations." It encompasses the time period between 2003 and the first 2 quarters of 2007 and establishes a baseline rate of events suggestive of swallowing difficulty for comparing to future reporting rates.

The current submission is a follow-up report covering the period July 1, 2007 to December 30, 2007 (**Attachment 1**). This report concludes that there may be a temporal relationship between the decline in the reporting rates and ratios of events suggestive of swallowing difficulties for the third and fourth quarter 2007 and the voluntary education campaign implemented by McNeil in July 2007.

The data and information contained in this submission constitute trade secrets and confidential commercial information (see 21 C.F.R. 20.61). McNeil Consumer Healthcare, a division of McNEIL-PPC, Inc hereby claims the legal protections afforded such trade secret and confidential information under 5.U.S.C. 552(b), 21 U.S.C. 331(j) and 18 U.S.C. 1905. Further dissemination may only be made with the express written permission of McNeil Consumer Healthcare, a division of McNeIL-PPC, Inc.

J&J BRM will continue quarterly monitoring of rates for events suggestive of swallowing difficulty and McNeil will submit the updates to FDA on a regular basis.

Please contact me if you have any questions or require additional information, at 215-273-8278 or in my absence, Lynn Pawelski, Vice President, Regulatory Affairs at 215-273-7731.

Sincerely,

MCNEIL CONSUMER HEALTHCARE

V. Wagner & Velen

Victoria M. Wagner-Weber

Director, Global Regulatory Affairs

cc: Neel Patel, Regulatory Project Manager



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JAN 2 8 2008

Andrea Leonard-Segal, MD, Director Food and Drug Administration Center for Drug Evaluation and Research Office of Nonprescription Products (HFD-560) Division of Nonprescription Clinical Evaluation Document Control Room 5901-B Ammendale Road Beltsville, MD 20705-1266

JAN 29 2008

CDER COR

SUPPL NEW CORRESP Sch-029(C)

RE:

NDA 19-872/S-029

Tylenol® 8-Hour (650 mg acetaminophen) extended-release tablets

Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release tablets

Geltabs Swallowability Improvement Program:

Voluntary Post Marketing Commitment - Reformulation Timeline

Dear Dr. Leonard-Segal:

Please refer to the meeting held between FDA and McNeil Consumer Healthcare ("McNeil") on May 22, 2007 and to McNeil's May 25, 2007 correspondence to FDA containing McNeil's action plan to address the swallowability of Tylenol® Arthritis Pain Relief "TAR" Geltabs. Please also refer to McNeil's submission of September 24, 2007 containing a status update on the swallowability improvement program; to revised labeling submitted on December 6, 2007 for TAR Geltabs; and to the January 14, 2008 submission containing a status update and background information for a scheduled teleconference with FDA on February 1, 2008. As discussed on January 24, 2008 with Neel Patel, PharmD, Regulatory Project Manager, Division of Nonprescription Evaluation, Office of Nonprescription Products, FDA has requested of McNeil a letter committing to the reformulation timeline. In response to FDA's request of January 24, 2008, McNeil is making this written commitment to the reformulation timeline submitted on January 14, 2008. (Attachment 1).

As reflected in the timeline, the action plan to address the swallowability of TAR Geltabs is already underway. The supplemental application for the reformulated product is estimated to be submitted in second quarter of 2009 and, pending agency approval, the reformulated product launch is projected to be introduced into the marketplace in early 2010; at that time, the current Tylenol extended-release gelatin-coated tablet will be

The data and information contained in this submission constitute trade secrets and confidential commercial information (see 21 C.F.R. 20.61). McNeil Consumer Healthcare, a division of McNEIL-PPC, Inc hereby claims the legal protections afforded such trade secret and confidential information under 5.U.S.C. 552(b), 21 U.S.C. 331(j) and 18 U.S.C. 1905. Further dissemination may only be made with the express written permission of McNeil Consumer Healthcare, a division of McNeIL-PPC, Inc.

discontinued. There will be at least a two year period of continued quarterly reporting of adverse events suggestive of swallowing difficulties after launching the reformulated product. McNeil will continue to provide FDA with periodic updated on the progress of the reformulation and will notify the agency if there are any challenges to development that may negatively impact the timeline. McNeil understands that the February 1, 2008 teleconference is no longer necessary and will be cancelled.

Please contact me if you have any questions or require additional information, at 215-273-8278 or in my absence, Lynn Pawelski, Vice President, Regulatory Affairs at 215-273-7731.

Sincerely,

MCNEIL CONSUMER HEALTHCARE

Victoria M. Wagner-Weber

Director, Global Regulatory Affairs

cc: Neel Patel, Regulatory Project Manager

Stagner Steller



ORIGINAL FEB 1 5 2008

Andrea Leonard-Segal, MD, Director Food and Drug Administration Center for Drug Evaluation and Research Office of Nonprescription Products (HFD-560) Division of Nonprescription Clinical Evaluation Document Control Room 5901-B Ammendale Road Beltsville, MD 20705-1266 RECEIVED

FEB 19 2008

CDER CDR

SLE-029-6F

RE:

NDA 19-872/S-029

Tylenol® 8-Hour (650 mg acetaminophen) extended-release tablets
Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release tablets

Final Printed Labeling (FPL)

SUPPLEMENT AMENDMENT

SLR-OJA(BF)

Dear Dr. Leonard-Segal:

Please refer to the NDA 19-872/S-029 for Tylenol® 8-Hour (650 mg acetaminophen) extended-release tablets and Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release tablets. Supplement 029 delineates label changes to address swallowability issues associated with Tylenol® Arthritis Pain Relief (650 mg acetaminophen) extended-release geltabs ("TAR geltabs"). These label changes were first discussed during a meeting held between FDA and McNeil Consumer Healthcare ("McNeil") on May 22, 2007 and have been the subject of correspondences dated May 25, 2007, July 31, 2007, August 30, 2007, September 24, 2007, October 2, 2007, December 6, 2007, December 17, 2007, January 14, 2008, January 25, 2008, and January 28, 2008.

At this time, McNeil is submitting the FPL for the 20-, 40-, and 80-count package sizes of TAR geltabs electronically, in accordance with the Guidance for Industry - Providing Regulatory Submissions in Electronic Format – General Considerations (January 1999). A CD-ROM is included in both the Archival and Review copies of this submission. The files were scanned with McAffee Virus Scan Enterprise, Version 8.0.0.912, Virus Definitions 4.0.5227, Scan Engine 5.200 and are virus free.

Specifically, the labeling for TAR geltabs has been revised as follows:

- 1. Principal Display Panel (PDP)
 - The statement "See New Warnings and Directions" is added to the primary PDP
 of the carton and to the PDP of the bottle label. This statement is printed in bold
 type and its size is one-third the size of the most prominent printed matter on the

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- primary PDP of the carton. McNeil commits to maintaining this statement on the PDP until the swallowability issue is adequately resolved.
- Per October 2, 2007 Discipline Review Letter (DRL), "fever reducer" has been added to the statement of identity (SOI).
- Per FDA's December 17, 2007 electronic request from Neel Patel, PharmD,
 Project Manager, the font size of the SOI has been increased.

2. Drug Facts Panel (Carton)

- Under "Purpose", "fever reducer" has been added to "pain reliever".
- Under ""Uses", "temporarily reduces fever" has been added.
- Under "Warnings", "Do not use" subheading, the statement "if you have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets." is added as the second bullet.
- Under "Warnings", "Stop use and ask a doctor if" subheading, the statement "the tablet got stuck in your throat" is added as the first bullet.
- Under "Directions":
 - The first bulleted statement "take 2 geltabs every 8 hours with water." is revised to read, "take 2 geltabs every 8 hours. Swallow only one geltab at a time."
 - The statement "take a sip of water before swallowing each geltab and wash each geltab down with water (up to a full 8 oz. glass)" is added as the second bullet.

3. Bottle Label

 To maintain consistency, the bottle label is also revised to include the same language as the Drug Facts label on the carton.

If you have any questions, please contact me at 215-273-8278 (fax: 215-273-4123), or in my absence, Lynn Pawelski, Vice President, Regulatory Affairs at 215-273-7731.

Sincerely,

MCNEIL CONSUMER HEALTHCARE

Victoria M. Wagner-Weber

Director, Global Regulatory Affairs

cc: Neel Patel, Regulatory Project Manager