

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

201803Orig1s000

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**

EXCLUSIVITY SUMMARY

NDA # 201803

SUPPL #

HFD #

Trade Name Advil

Generic Name sodium ibuprofen dihydrate, 256 mg

Applicant Name Pfizer Consumer Healthcare

Approval Date, If Known June 12, 2012

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, and all efficacy supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES NO

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3, SE4, SE5, SE6, SE7, SE8

505(b)(2)

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES NO

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

This submission contains a PK study comparing ibuprofen sodium tablet to Advil® liqui-gel (NDA 020402) and Motrin® IB tablet (NDA 19012) in the fed and fasted state. The sponsor did not disagree with the Agency regarding the type of study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

d) Did the applicant request exclusivity?

YES NO

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

e) Has pediatric exclusivity been granted for this Active Moiety?

YES NO

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

2. Is this drug product or indication a DESI upgrade?

YES NO

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# 19012 Motrin IB tablet

NDA# 18989 Advil tablet

NDA# 20402 Advil liqui gels

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#

NDA#

NDA#

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. (Caution: The questions in part II of the summary should only be answered "NO" for original approvals of new molecular entities.)
IF "YES," GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDAs AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of

summary for that investigation.

YES NO

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES NO

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES NO

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES NO

If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES NO

If yes, explain:

- (c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES NO

Investigation #2 YES NO

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES NO

Investigation #2 YES NO

If you have answered "yes" for one or more investigation, identify the NDA in which a

Explain:

! Explain:

Investigation #2

!

!

YES

! NO

Explain:

! Explain:

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES

NO

If yes, explain:

=====

Name of person completing form: LT James Lee

Title: Regulatory Project Manager

Date: 05/15/12

Name of Office/Division Director signing form: Joel Schiffenbauer, MD

Title: Deputy Director

Form OGD-011347; Revised 05/10/2004; formatted 2/15/05

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

/s/

JAMES C LEE
06/15/2012

JOEL SCHIFFENBAUER
06/15/2012

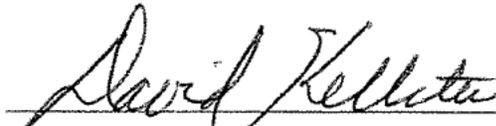
Sodium Ibuprofen, 200 mg

1.3 Administrative Information
1.3.3 Debarment Certification

1.3.3 Debarment Certification

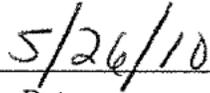
Pfizer Consumer Health hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of Federal Food, Drug and Cosmetic Act in connection with this application, Advil[®] (b)(4), NDA 201803.

Pfizer Consumer Healthcare



David Kellstein, Ph.D.

Director, Clinical and Medical Affairs



Date

ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION ¹		
NDA # 201803 BLA #	NDA Supplement # BLA Supplement #	If NDA, Efficacy Supplement Type:
Proprietary Name: Advil Established/Proper Name: ibuprofen tablets, 200 mg (provided as ibuprofen sodium, 256 mg) Dosage Form: tablet		Applicant: Pfizer Consumer Healthcare Agent for Applicant (if applicable):
RPM: James Lee		Division: DNCE
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><u>NDA and NDA Efficacy Supplements:</u></p> <p>NDA Application Type: <input type="checkbox"/> 505(b)(1) <input checked="" type="checkbox"/> 505(b)(2) Efficacy Supplement: <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)</p> <p>(A supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2). Consult page 1 of the 505(b)(2) Assessment or the Appendix to this Action Package Checklist.)</p> </div> <div style="width: 50%;"> <p><u>505(b)(2) Original NDAs and 505(b)(2) NDA supplements:</u></p> <p>Listed drug(s) relied upon for approval (include NDA #(s) and drug name(s):</p> <p>NDA 019012 Motrin IB tablet</p> <p>Provide a brief explanation of how this product is different from the listed drug.</p> <p>New ibuprofen salt that provides faster absorption, and potentially faster onset of analgesia than standard ibuprofen</p> <p><input type="checkbox"/> This application does not reply upon a listed drug. <input type="checkbox"/> This application relies on literature. <input type="checkbox"/> This application relies on a final OTC monograph. <input type="checkbox"/> This application relies on (explain)</p> <p><u>For ALL (b)(2) applications, two months prior to EVERY action, review the information in the 505(b)(2) Assessment and submit the draft² to CDER OND IO for clearance. Finalize the 505(b)(2) Assessment at the time of the approval action.</u></p> <p><u>On the day of approval, check the Orange Book again for any new patents or pediatric exclusivity.</u></p> <p><input type="checkbox"/> No changes <input type="checkbox"/> Updated Date of check:</p> <p>If pediatric exclusivity has been granted or the pediatric information in the labeling of the listed drug changed, determine whether pediatric information needs to be added to or deleted from the labeling of this drug.</p> </div> </div>		
❖ Actions		
<ul style="list-style-type: none"> Proposed action User Fee Goal Date is <u>June 16, 2012</u> Previous actions (<i>specify type and date for each action taken</i>) 		<input checked="" type="checkbox"/> AP <input type="checkbox"/> TA <input type="checkbox"/> CR <input type="checkbox"/> None CR: April 29, 2011

¹ The **Application Information** Section is (only) a checklist. The **Contents of Action Package** Section (beginning on page 5) lists the documents to be included in the Action Package.

² For resubmissions, (b)(2) applications must be cleared before the action, but it is not necessary to resubmit the draft 505(b)(2) Assessment to CDER OND IO unless the Assessment has been substantively revised (e.g., new listed drug, patent certification revised).

<p>❖ If accelerated approval or approval based on efficacy studies in animals, were promotional materials received? Note: Promotional materials to be used within 120 days after approval must have been submitted (for exceptions, see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf). If not submitted, explain _____</p>	<input type="checkbox"/> Received
<p>❖ Application Characteristics ³</p>	
<p>Review priority: <input checked="" type="checkbox"/> Standard <input type="checkbox"/> Priority Chemical classification (new NDAs only): 2</p> <p> <input type="checkbox"/> Fast Track <input type="checkbox"/> Rx-to-OTC full switch <input type="checkbox"/> Rolling Review <input type="checkbox"/> Rx-to-OTC partial switch <input type="checkbox"/> Orphan drug designation <input checked="" type="checkbox"/> Direct-to-OTC </p> <p> NDAs: Subpart H <input type="checkbox"/> Accelerated approval (21 CFR 314.510) <input type="checkbox"/> Restricted distribution (21 CFR 314.520) Subpart I <input type="checkbox"/> Approval based on animal studies </p> <p> <input type="checkbox"/> Submitted in response to a PMR <input type="checkbox"/> Submitted in response to a PMC <input type="checkbox"/> Submitted in response to a Pediatric Written Request </p> <p> BLAs: Subpart E <input type="checkbox"/> Accelerated approval (21 CFR 601.41) <input type="checkbox"/> Restricted distribution (21 CFR 601.42) Subpart H <input type="checkbox"/> Approval based on animal studies </p> <p> REMS: <input type="checkbox"/> MedGuide <input type="checkbox"/> Communication Plan <input type="checkbox"/> ETASU <input type="checkbox"/> MedGuide w/o REMS <input type="checkbox"/> REMS not required </p> <p>Comments:</p>	
<p>❖ BLAs only: Ensure <i>RMS-BLA Product Information Sheet for TBP</i> and <i>RMS-BLA Facility Information Sheet for TBP</i> have been completed and forwarded to OPI/OBI/DRM (Vicky Carter)</p>	<input type="checkbox"/> Yes, dates
<p>❖ BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 (<i>approvals only</i>)</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>❖ Public communications (<i>approvals only</i>)</p>	
<ul style="list-style-type: none"> Office of Executive Programs (OEP) liaison has been notified of action 	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<ul style="list-style-type: none"> Press Office notified of action (by OEP) 	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<ul style="list-style-type: none"> Indicate what types (if any) of information dissemination are anticipated 	<input checked="" type="checkbox"/> None <input type="checkbox"/> HHS Press Release <input type="checkbox"/> FDA Talk Paper <input type="checkbox"/> CDER Q&As <input type="checkbox"/> Other

³ Answer all questions in all sections in relation to the pending application, i.e., if the pending application is an NDA or BLA supplement, then the questions should be answered in relation to that supplement, not in relation to the original NDA or BLA. For example, if the application is a pending BLA supplement, then a new *RMS-BLA Product Information Sheet for TBP* must be completed.

❖ Exclusivity	
<ul style="list-style-type: none"> Is approval of this application blocked by any type of exclusivity? 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
<ul style="list-style-type: none"> NDA and BLAs: Is there existing orphan drug exclusivity for the “same” drug or biologic for the proposed indication(s)? <i>Refer to 21 CFR 316.3(b)(13) for the definition of “same drug” for an orphan drug (i.e., active moiety). This definition is NOT the same as that used for NDA chemical classification.</i> 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If, yes, NDA/BLA # and date exclusivity expires:
<ul style="list-style-type: none"> (b)(2) NDAs only: Is there remaining 5-year exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date exclusivity expires:
<ul style="list-style-type: none"> (b)(2) NDAs only: Is there remaining 3-year exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date exclusivity expires:
<ul style="list-style-type: none"> (b)(2) NDAs only: Is there remaining 6-month pediatric exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date exclusivity expires:
<ul style="list-style-type: none"> NDAs only: Is this a single enantiomer that falls under the 10-year approval limitation of 505(u)? <i>(Note that, even if the 10-year approval limitation period has not expired, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date 10-year limitation expires:
❖ Patent Information (NDAs only)	
<ul style="list-style-type: none"> Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought. If the drug is an old antibiotic, skip the Patent Certification questions. 	<input checked="" type="checkbox"/> Verified <input type="checkbox"/> Not applicable because drug is an old antibiotic.
<ul style="list-style-type: none"> Patent Certification [505(b)(2) applications]: Verify that a certification was submitted for each patent for the listed drug(s) in the Orange Book and identify the type of certification submitted for each patent. 	21 CFR 314.50(i)(1)(i)(A) <input checked="" type="checkbox"/> Verified 21 CFR 314.50(i)(1) <input type="checkbox"/> (ii) <input type="checkbox"/> (iii)
<ul style="list-style-type: none"> [505(b)(2) applications] If the application includes a paragraph III certification, it cannot be approved until the date that the patent to which the certification pertains expires (but may be tentatively approved if it is otherwise ready for approval). 	<input checked="" type="checkbox"/> No paragraph III certification Date patent will expire
<ul style="list-style-type: none"> [505(b)(2) applications] For each paragraph IV certification, verify that the applicant notified the NDA holder and patent owner(s) of its certification that the patent(s) is invalid, unenforceable, or will not be infringed (review documentation of notification by applicant and documentation of receipt of notice by patent owner and NDA holder). <i>(If the application does not include any paragraph IV certifications, mark “N/A” and skip to the next section below (Summary Reviews)).</i> 	<input checked="" type="checkbox"/> N/A (no paragraph IV certification) <input type="checkbox"/> Verified

- [505(b)(2) applications] For **each paragraph IV** certification, based on the questions below, determine whether a 30-month stay of approval is in effect due to patent infringement litigation.

Answer the following questions for **each** paragraph IV certification:

- (1) Have 45 days passed since the patent owner's receipt of the applicant's notice of certification?

Yes No

(Note: The date that the patent owner received the applicant's notice of certification can be determined by checking the application. The applicant is required to amend its 505(b)(2) application to include documentation of this date (e.g., copy of return receipt or letter from recipient acknowledging its receipt of the notice) (see 21 CFR 314.52(e)).

If "Yes," skip to question (4) below. If "No," continue with question (2).

- (2) Has the patent owner (or NDA holder, if it is an exclusive patent licensee) submitted a written waiver of its right to file a legal action for patent infringement after receiving the applicant's notice of certification, as provided for by 21 CFR 314.107(f)(3)?

Yes No

If "Yes," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip the rest of the patent questions.

If "No," continue with question (3).

- (3) Has the patent owner, its representative, or the exclusive patent licensee filed a lawsuit for patent infringement against the applicant?

Yes No

(Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)).

If "No," the patent owner (or NDA holder, if it is an exclusive patent licensee) has until the expiration of the 45-day period described in question (1) to waive its right to bring a patent infringement action or to bring such an action. After the 45-day period expires, continue with question (4) below.

- (4) Did the patent owner (or NDA holder, if it is an exclusive patent licensee) submit a written waiver of its right to file a legal action for patent infringement within the 45-day period described in question (1), as provided for by 21 CFR 314.107(f)(3)?

Yes No

If "Yes," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next section below (Summary Reviews).

If "No," continue with question (5).

<p>(5) Did the patent owner, its representative, or the exclusive patent licensee bring suit against the (b)(2) applicant for patent infringement within 45 days of the patent owner's receipt of the applicant's notice of certification?</p> <p>(Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)). If no written notice appears in the NDA file, confirm with the applicant whether a lawsuit was commenced within the 45-day period).</p> <p><i>If "No," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next section below (Summary Reviews).</i></p> <p><i>If "Yes," a stay of approval may be in effect. To determine if a 30-month stay is in effect, consult with the OND ADRA and attach a summary of the response.</i></p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
CONTENTS OF ACTION PACKAGE	
<p>❖ Copy of this Action Package Checklist⁴</p>	
Officer/Employee List	
<p>❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list (<i>approvals only</i>)</p>	<p><input checked="" type="checkbox"/> Included</p>
<p>Documentation of consent/non-consent by officers/employees</p>	<p><input checked="" type="checkbox"/> Included</p>
Action Letters	
<p>❖ Copies of all action letters (<i>including approval letter with final labeling</i>)</p>	<p>Action(s) and date(s) Approval 06/12/12; Complete response April 29, 2011</p>
Labeling	
<p>❖ Package Insert (<i>write submission/communication date at upper right of first page of PI</i>)</p>	
<ul style="list-style-type: none"> • Most recent draft labeling. If it is division-proposed labeling, it should be in track-changes format. 	
<ul style="list-style-type: none"> • Original applicant-proposed labeling 	
<ul style="list-style-type: none"> • Example of class labeling, if applicable 	

⁴ Fill in blanks with dates of reviews, letters, etc.

<ul style="list-style-type: none"> ❖ Medication Guide/Patient Package Insert/Instructions for Use/Device Labeling (<i>write submission/communication date at upper right of first page of each piece</i>) 	<input type="checkbox"/> Medication Guide <input type="checkbox"/> Patient Package Insert <input type="checkbox"/> Instructions for Use <input type="checkbox"/> Device Labeling <input checked="" type="checkbox"/> None
<ul style="list-style-type: none"> • Most-recent draft labeling. If it is division-proposed labeling, it should be in track-changes format. • Original applicant-proposed labeling • Example of class labeling, if applicable 	
<ul style="list-style-type: none"> ❖ Labels (full color carton and immediate-container labels) (<i>write submission/communication date on upper right of first page of each submission</i>) 	
<ul style="list-style-type: none"> • Most-recent draft labeling 	April 15, and 22, 2011
<ul style="list-style-type: none"> ❖ Proprietary Name <ul style="list-style-type: none"> • Acceptability/non-acceptability letter(s) (<i>indicate date(s)</i>) • Review(s) (<i>indicate date(s)</i>) • Ensure that both the proprietary name(s), if any, and the generic name(s) are listed in the Application Product Names section of DARRTS, and that the proprietary/trade name is checked as the 'preferred' name. 	Accepted: April 28, 2011
<ul style="list-style-type: none"> ❖ Labeling reviews (<i>indicate dates of reviews and meetings</i>) 	<input type="checkbox"/> RPM <input type="checkbox"/> DMEPA <input type="checkbox"/> DMPP/PLT (DRISK) <input type="checkbox"/> ODPD (DDMAC) <input type="checkbox"/> SEALD <input type="checkbox"/> CSS <input type="checkbox"/> Other reviews DNRD Review: April 15, and 22, 2011
Administrative / Regulatory Documents	
<ul style="list-style-type: none"> ❖ Administrative Reviews (<i>e.g., RPM Filing Review⁵/Memo of Filing Meeting</i>) (<i>indicate date of each review</i>) ❖ All NDA (b)(2) Actions: Date each action cleared by (b)(2) Clearance Cmte ❖ NDA (b)(2) Approvals Only: 505(b)(2) Assessment (<i>indicate date</i>) 	RPM Filing Review: 09/17/10 <input type="checkbox"/> Not a (b)(2) 05/21/12; April 11, 2011 <input type="checkbox"/> Not a (b)(2) 06/18/12
<ul style="list-style-type: none"> ❖ NDAs only: Exclusivity Summary (<i>signed by Division Director</i>) 	<input checked="" type="checkbox"/> Included
<ul style="list-style-type: none"> ❖ Application Integrity Policy (AIP) Status and Related Documents http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm 	
<ul style="list-style-type: none"> • Applicant is on the AIP 	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<ul style="list-style-type: none"> • This application is on the AIP <ul style="list-style-type: none"> ○ If yes, Center Director's Exception for Review memo (<i>indicate date</i>) ○ If yes, OC clearance for approval (<i>indicate date of clearance communication</i>) 	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not an AP action
<ul style="list-style-type: none"> ❖ Pediatrics (<i>approvals only</i>) <ul style="list-style-type: none"> • Date reviewed by PeRC <u>04/06/11</u> If PeRC review not necessary, explain: _____ • Pediatric Page/Record (<i>approvals only, must be reviewed by PERC before finalized</i>) 	<input checked="" type="checkbox"/> Included

⁵ Filing reviews for scientific disciplines should be filed behind the respective discipline tab.

❖ Debarment certification (original applications only): verified that qualifying language was not used in certification and that certifications from foreign applicants are cosigned by U.S. agent <i>(include certification)</i>	<input checked="" type="checkbox"/> Verified, statement is acceptable
❖ Outgoing communications <i>(letters, including response to FD RR (do not include previous action letters in this tab), emails, faxes, telecons)</i>	09/15/11; 09/01/11; 06/28/11; 04/20/11; 02/22/11; 02/17/11; 01/28/11; 01/10/11; 12/15/10; 10/13/10
❖ Internal memoranda, telecons, etc.	03/22/11
❖ Minutes of Meetings	
• Regulatory Briefing <i>(indicate date of mtg)</i>	<input checked="" type="checkbox"/> No mtg
• If not the first review cycle, any end-of-review meeting <i>(indicate date of mtg)</i>	<input checked="" type="checkbox"/> N/A or no mtg
• Pre-NDA/BLA meeting <i>(indicate date of mtg)</i>	<input type="checkbox"/> No mtg 12/15/09
• EOP2 meeting <i>(indicate date of mtg)</i>	<input checked="" type="checkbox"/> No mtg
• Other milestone meetings (e.g., EOP2a, CMC pilots) <i>(indicate dates of mtgs)</i>	
❖ Advisory Committee Meeting(s)	<input checked="" type="checkbox"/> No AC meeting
• Date(s) of Meeting(s)	
• 48-hour alert or minutes, if available <i>(do not include transcript)</i>	
Decisional and Summary Memos	
❖ Office Director Decisional Memo <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> None
Division Director Summary Review <i>(indicate date for each review)</i>	<input type="checkbox"/> None 06/12/12
Cross-Discipline Team Leader Review <i>(indicate date for each review)</i>	<input type="checkbox"/> None 03/14/11
PMR/PMC Development Templates <i>(indicate total number)</i>	<input checked="" type="checkbox"/> None
Clinical Information⁶	
❖ Clinical Reviews	
• Clinical Team Leader Review(s) <i>(indicate date for each review)</i>	03/14/11
• Clinical review(s) <i>(indicate date for each review)</i>	03/14/12; 02/25/11; 08/05/10;
• Social scientist review(s) (if OTC drug) <i>(indicate date for each review)</i>	<input checked="" type="checkbox"/> None
❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here <input type="checkbox"/> and include a review/memo explaining why not <i>(indicate date of review/memo)</i>	Page 10 of Clinical Review 03/14/12
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers <i>(indicate date of each review)</i>	<input checked="" type="checkbox"/> None
❖ Controlled Substance Staff review(s) and Scheduling Recommendation <i>(indicate date of each review)</i>	<input checked="" type="checkbox"/> Not applicable

⁶ Filing reviews should be filed with the discipline reviews.

❖ Risk Management <ul style="list-style-type: none"> REMS Documents and Supporting Statement (<i>indicate date(s) of submission(s)</i>) REMS Memo(s) and letter(s) (<i>indicate date(s)</i>) Risk management review(s) and recommendations (including those by OSE and CSS) (<i>indicate date of each review and indicate location/date if incorporated into another review</i>) 	<input checked="" type="checkbox"/> None
❖ DSI Clinical Inspection Review Summary(ies) (<i>include copies of DSI letters to investigators</i>)	<input type="checkbox"/> None requested
Clinical Microbiology <input checked="" type="checkbox"/> None	
❖ Clinical Microbiology Team Leader Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Clinical Microbiology Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Biostatistics <input checked="" type="checkbox"/> None	
❖ Statistical Division Director Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Statistical Team Leader Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Statistical Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Clinical Pharmacology <input type="checkbox"/> None	
❖ Clinical Pharmacology Division Director Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Clinical Pharmacology Team Leader Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Clinical Pharmacology review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None 03/01/11
❖ DSI Clinical Pharmacology Inspection Review Summary (<i>include copies of DSI letters</i>)	<input type="checkbox"/> None 01/25/11
Nonclinical <input type="checkbox"/> None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
• Supervisory Review(s) (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
• Pharm/tox review(s), including referenced IND reviews (<i>indicate date for each review</i>)	<input type="checkbox"/> None 05/03/012; 03/01/11; 08/30/10
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> None
❖ Statistical review(s) of carcinogenicity studies (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> No carc
❖ ECAC/CAC report/memo of meeting	<input checked="" type="checkbox"/> None Included in P/T review, page
❖ DSI Nonclinical Inspection Review Summary (<i>include copies of DSI letters</i>)	<input checked="" type="checkbox"/> None requested

Product Quality		<input type="checkbox"/> None
❖ Product Quality Discipline Reviews		
• ONDQA/OBP Division Director Review(s) <i>(indicate date for each review)</i>		<input type="checkbox"/> None
• Branch Chief/Team Leader Review(s) <i>(indicate date for each review)</i>		<input type="checkbox"/> None
• Product quality review(s) including ONDQA biopharmaceutics reviews <i>(indicate date for each review)</i>		<input type="checkbox"/> None 02/09/12; 04/26/11; 11/08/10; 08/04/10
❖ Microbiology Reviews		<input type="checkbox"/> Not needed
<input type="checkbox"/> NDAs: Microbiology reviews (sterility & pyrogenicity) (OPS/NDMS) <i>(indicate date of each review)</i>		
<input type="checkbox"/> BLAs: Sterility assurance, microbiology, facilities reviews (OMPQ/MAPCB/BMT) <i>(indicate date of each review)</i>		
❖ Reviews by other disciplines/divisions/Centers requested by CMC/quality reviewer <i>(indicate date of each review)</i>		<input type="checkbox"/> None 02/28/11; 02/15/11
❖ Environmental Assessment (check one) (original and supplemental applications)		
<input type="checkbox"/> Categorical Exclusion <i>(indicate review date)(all original applications and all efficacy supplements that could increase the patient population)</i>		
<input type="checkbox"/> Review & FONSI <i>(indicate date of review)</i>		
<input type="checkbox"/> Review & Environmental Impact Statement <i>(indicate date of each review)</i>		
❖ Facilities Review/Inspection		
<input checked="" type="checkbox"/> NDAs: Facilities inspections (include EER printout) <i>(date completed must be within 2 years of action date) (only original NDAs and supplements that include a new facility or a change that affects the manufacturing sites⁷)</i>		Date completed: 12/06/11 <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Withhold recommendation <input type="checkbox"/> Not applicable
<input type="checkbox"/> BLAs: TB-EER <i>(date of most recent TB-EER must be within 30 days of action date) (original and supplemental BLAs)</i>		Date completed: <input type="checkbox"/> Acceptable <input type="checkbox"/> Withhold recommendation
❖ NDAs: Methods Validation <i>(check box only, do not include documents)</i>		<input type="checkbox"/> Completed <input type="checkbox"/> Requested <input type="checkbox"/> Not yet requested <input checked="" type="checkbox"/> Not needed (per review)

⁷ I.e., a new facility or a change in the facility, or a change in the manufacturing process in a way that impacts the Quality Management Systems of the facility.

Appendix to Action Package Checklist

An NDA or NDA supplemental application is likely to be a 505(b)(2) application if:

- (1) It relies on published literature to meet any of the approval requirements, and the applicant does not have a written right of reference to the underlying data. If published literature is cited in the NDA but is not necessary for approval, the inclusion of such literature will not, in itself, make the application a 505(b)(2) application.
- (2) **Or** it relies for approval on the Agency's previous findings of safety and efficacy for a listed drug product and the applicant does not own or have right to reference the data supporting that approval.
- (3) **Or** it relies on what is "generally known" or "scientifically accepted" about a class of products to support the safety or effectiveness of the particular drug for which the applicant is seeking approval. (Note, however, that this does not mean *any* reference to general information or knowledge (e.g., about disease etiology, support for particular endpoints, methods of analysis) causes the application to be a 505(b)(2) application.)

Types of products for which 505(b)(2) applications are likely to be submitted include: fixed-dose combination drug products (e.g., heart drug and diuretic (hydrochlorothiazide) combinations); OTC monograph deviations (see 21 CFR 330.11); new dosage forms; new indications; and, new salts.

An efficacy supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2).

An efficacy supplement is a 505(b)(1) supplement if the supplement contains all of the information needed to support the approval of the change proposed in the supplement. For example, if the supplemental application is for a new indication, the supplement is a 505(b)(1) if:

- (1) The applicant has conducted its own studies to support the new indication (or otherwise owns or has right of reference to the data/studies).
- (2) **And** no additional information beyond what is included in the supplement or was embodied in the finding of safety and effectiveness for the original application or previously approved supplements is needed to support the change. For example, this would likely be the case with respect to safety considerations if the dose(s) was/were the same as (or lower than) the original application.
- (3) **And** all other "criteria" are met (e.g., the applicant owns or has right of reference to the data relied upon for approval of the supplement, the application does not rely for approval on published literature based on data to which the applicant does not have a right of reference).

An efficacy supplement is a 505(b)(2) supplement if:

- (1) Approval of the change proposed in the supplemental application would require data beyond that needed to support our previous finding of safety and efficacy in the approval of the original application (or earlier supplement), and the applicant has not conducted all of its own studies for approval of the change, or obtained a right to reference studies it does not own. For example, if the change were for a new indication AND a higher dose, we would likely require clinical efficacy data and preclinical safety data to approve the higher dose. If the applicant provided the effectiveness data, but had to rely on a different listed drug, or a new aspect of a previously cited listed drug, to support the safety of the new dose, the supplement would be a 505(b)(2).
- (2) **Or** the applicant relies for approval of the supplement on published literature that is based on data that the applicant does not own or have a right to reference. If published literature is cited in the supplement but is not necessary for approval, the inclusion of such literature will not, in itself, make the supplement a 505(b)(2) supplement.
- (3) **Or** the applicant is relying upon any data they do not own or to which they do not have right of reference.

If you have questions about whether an application is a 505(b)(1) or 505(b)(2) application, consult with your ODE's ADRA.

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/s/

JAMES C LEE
06/18/2012



NDA 201803

**ACKNOWLEDGE –
CLASS 2 RESPONSE**

Pfizer Consumer Healthcare
Attention: Kevin N. Hibbert, MD, MPH
Director, North American Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Dr. Hibbert:

We acknowledge receipt on December 16, 2011, of your December 16, 2011, resubmission of your new drug application submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Advil (sodium ibuprofen) tablet, 256 mg.

We consider this a complete, class 2 response to our April 29, 2011, action letter. Therefore, the user fee goal date is June 16, 2012.

If you have any questions, call LT James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

LT James Lee, PharmD
Regulatory Project Manager
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

JAMES C LEE
05/02/2012



NDA 201803

INFORMATION REQUEST

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Pfizer Consumer Healthcare
Attention: Lauren Quinn, J.D.
Sr. Director, North America Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Quinn:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil[®] (ibuprofen) tablet, 200 mg [provided as ibuprofen sodium, 256 mg].

FDA investigators have identified significant violations to the bioavailability and bioequivalence requirements of Title 21, Code of Federal Regulation, Part 320 in bioanalytical studies conducted by Cetero Research in Houston, Texas (Cetero).¹ The pervasiveness and egregious nature of the violative practices by Cetero has led FDA to have significant concerns that the bioanalytical data generated at Cetero from April 1, 2005 to June 15, 2010, as part of studies submitted to FDA in New Drug Applications (NDA) and Supplemental New Drug Applications (sNDA) are unreliable. FDA has reached this conclusion for three reasons: (1) the widespread falsification of dates and times in laboratory records for subject sample extractions, (2) the apparent manipulation of equilibration or “prep” run samples to meet pre-determined acceptance criteria, and (3) lack of documentation regarding equilibration or “prep” runs that prevented Cetero and the Agency from determining the extent and impact of these violations.

Serious questions remain about the validity of any data generated in studies by Cetero Research in Houston, Texas during this time period. In view of these findings, FDA is informing holders of approved and pending NDAs of these issues.

The impact of the data from these studies (which may include bioequivalence, bioavailability, drug-drug interaction, specific population, and others) cannot be assessed without knowing the details regarding the study and how the data in question were considered in the overall development and approval of your drug product. At this time, the Office of New Drugs is

¹ These violations include studies conducted by Bioassay Laboratories and BA Research International specific to the Houston, Texas facility.

searching available documentation to determine which NDAs are impacted by the above findings.

To further expedite this process, we ask that you inform us if you have submitted any studies conducted by Cetero Research in Houston, Texas during the time period of concern (April 1, 2005 to June 15, 2010). Please submit information on each of the studies, including supplement number (if appropriate), study name/protocol number, and date of submission. With respect to those studies, you will need to do one of the following: (a) re-assay samples if available and supported by stability data, (b) repeat the studies, or (c) provide a rationale if you feel that no further action is warranted.

Please respond to this query within 30 days from the date of this letter.

This information should be submitted as correspondence to your NDA. In addition, please provide a desk copy to:

Office of New Drugs
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Bldg. 22, Room 6300
Silver Spring, MD 20993-0002

If you have any questions, call LT James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

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

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/s/

MELISSA H FURNESS

09/15/2011

Signing for Dr. Andrea Leonard-Segal



NDA 201803

FILING COMMUNICATION

Pfizer Consumer Healthcare
Attention: Yael Gozin, Ph.D.
Manager, Global Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Dr. Gozin:

Please refer to your new drug application (NDA) dated July 1, 2010, received July 1, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for Advil® (b)(4) (sodium ibuprofen (b)(4)) tablets, 256 mg.

We also refer to your submissions dated July 12 and 27, 2010.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, in accordance with 21 CFR 314.101(a), this application is considered filed 60 days after the date we received your application. The review classification for this application is **Standard**. Therefore, the user fee goal date is May 1, 2011

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, midcycle, team and wrap-up meetings). Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing commitment requests by March 25, 2011.

During our filing review of your application, we identified the following potential review issues and request that you submit the following information:

Labeling

1. Provide the (b)(4)-count immediate container (bottle) label.

2. Provide annotated specifications for the Drug Facts labels for all stock keeping units (SKUs) in accordance with 201.66(d).

We are providing the above comments to give you preliminary notice of potential review issues. Our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our review. Issues may be added, deleted, expanded upon, or modified as we review the application.

Please respond only to the above requests for additional information. While we anticipate that any response submitted in a timely manner will be reviewed during this review cycle, such review decisions will be made on a case-by-case basis at the time of receipt of the submission.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We acknowledge receipt of your request for a partial waiver of pediatric studies for this application. Once we have reviewed your request, we will notify you if the partial waiver request is denied.

If you have any questions, call James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

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

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-201803

ORIG-1

PFIZER
CONSUMER
HEALTHCARE

Advil (b) (4) (256 mg sodium
ibuprofen (b) (4))

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/s/

JOEL SCHIFFENBAUER
09/13/2010



NDA 201803

**PROPRIETARY NAME REQUEST
ACCEPTABLE**

Pfizer Consumer Healthcare
5 Giralda Farms
Madison, NJ 07940

ATTENTION: John Schalago
Director, Worldwide Regulatory Strategy

Dear Mr. Schalago;

Please refer to your New Drug Application (NDA) dated July 1, 2010, received July 1, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ibuprofen Tablets, 200 mg (provided as Ibuprofen Sodium 256 mg).

We also refer to your April 15, 2011, correspondence, received April 18, 2011, requesting review of your proposed proprietary name, Advil. We have completed our review of the proposed proprietary name, Advil, and have concluded that it is acceptable.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Cheryle Milburn, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-2084. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager, James Lee at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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/s/

CAROL A HOLQUIST
04/28/2011

Lee, James C.

From: Lee, James C.
Sent: Wednesday, April 20, 2011 12:48 PM
To: 'Gozin, Yael'
Subject: NDA 201803 Information Request

Dear Yael,

We are currently reviewing the labels submitted on Friday, April 15, 2011, for NDA 201803 and have the following information request:

Please submit the following labels for review:
PAA017732.FDA03, Carton (b) (4)-count (b) (4)

PAA017731.FDA03, Bottle (b) (4)-count (b) (4)

PAA017728.FDA01, Blister Card (b) (4)

If you have any questions, please contact me at your earliest convenience,

Regards,

James Lee

LT James Lee, PharmD.
United States Public Health Service
Regulatory Project Manager
FDA-CDER-ODEIV
Division of Nonprescription Clinical Evaluation
10903 New Hampshire Avenue, Bldg. 22, Room 5471
Silver Spring, MD 20903
Tel: 301-796-5283 Fax: 301-796-9850
Email: james.lee4@fda.hhs.gov

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/s/

JAMES C LEE
04/20/2011



NDA 201803

**PROPRIETARY NAME REQUEST
WITHDRAWN**

Pfizer Consumer Healthcare
5 Giralda Farms
Madison, New Jersey 07940

ATTENTION: Yael Gozin, Ph.D.
Manager, Global Regulatory Affairs

Dear Dr. Gozin:

Please refer to your New Drug Application (NDA) dated July 1, 2010, received July 1, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ibuprofen 200 mg (provided as Ibuprofen Sodium, 256 mg).

We acknowledge receipt of your March 31, 2011, correspondence, on April 1, 2011, notifying us that you are withdrawing your request for a review of the primary proposed proprietary name Advil (b) (4) and alternate proposed proprietary name Advil (b) (4). This proposed proprietary name request is considered withdrawn as of April 1, 2011.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Cheryle Milburn, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-2084. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager, James Lee at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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/s/

CAROL A HOLQUIST
04/04/2011

MEMORANDUM OF MEETING MINUTES

MEETING DATE: March 28, 2011
TIME: 1:00 PM-2:00 PM EST
LOCATION: White Oak Conference Room 4322
DRUG NAME: Advil (b) (4) NDA 201803 RCM# 2011-29
TYPE OF MEETING: Teleconference with Pfizer

MEETING CHAIR: Carol Holquist. Director, Division of Medication Error and Prevention Analysis (DMEPA), OSE

MEETING RECORDER: Cheryle Milburn, SRPM, OSE

FDA ATTENDEES: (Title and Office/Division)
Zachary Oleszczuk, Team Leader, DMEPA, OSE
Manizheh Siahpoushan, Safety Reviewer, DMEPA, OSE
Kellie Taylor, Associate Director, DMEPA, OSE

EXTERNAL CONSTITUENT ATTENDEES:

Lauren Quinn, JD-Senior Director, Worldwide Regulatory Strategy
Suzanne Brabant-Director, Worldwide Regulatory Strategy
Heather Storms-Senior product Manager, US Marketing
Kevin Homler-Senior Director, Global Marketing
David Kellstein, Ph.D.- Senior Director, R&D, Clinical Research
John Schalago-Director, Worldwide Regulatory Strategy
Peter Ramsey, Ph.D.-Senior Director, R&D
Yael Gozin, Ph.D. –Manager, Worldwide Regulatory Strategy

BACKGROUND:

Because of the approaching PDUFA date the Applicant submitted a list of possible names and naming strategies that the Applicant would consider pursuing. The Applicant asked that the FDA provide any feedback for options that would not be appropriate and if any of the options seems viable to the Agency.

MEETING OBJECTIVES:

- Discussion of Modifiers
 (b) (4)
 - “Name” by makers of Advil
 - Use of a prefix
- Steps Forward

DISCUSSION POINTS:

- PDUFA is May 1, 2011- Hope to have a name approved by that date.
- Pfizer discussed what they heard at the March 10 teleconference.
- Discussion of how the FDA evaluates the proprietary names and modifiers
- Walk through the rational for modifiers
- Pfizer would like parameters to work with in looking for a name.
- Pfizer would like an understanding of why DNCE group made this a new ingredient and they had to respond to PREA and DMEPA does not consider this a new ingredient.
- FDA discussed that in past we have not used salt formulations as a modifier in the name.
- FDA discussed that we do not use different standards for OTC drugs.

DECISIONS (AGREEMENTS) REACHED:

- Pfizer will send FDA letter of withdrawal for (b) (4) Advil (b) (4).

UNRESOLVED ISSUES OR ISSUES REQUIRING FURTHER DISCUSSION:

- Pfizer struggling with name options.

ACTION ITEMS:

- Pfizer will send a list of names to get response to see which names will get approval by PDUFA date.

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/s/

CHERYE D MILBURN
05/09/2011



NDA 201803

LABELING PMR/PMC DISCUSSION COMMENTS

Pfizer Consumer Healthcare
Attention: Yael Gozin, Ph.D.
Manager, Global Regulatory Affairs
5 Giralda Farms, Madison, NJ 07940

Dear Dr. Gozin:

Please refer to your July 1, 2010 New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ibuprofen sodium tablets, 256 mg.

We also refer to our September 13, 2010, letter in which we notified you of our target date of March 25, 2011 for communicating labeling changes and/or postmarketing requirements/commitments in accordance with the “PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES – FISCAL YEARS 2008 THROUGH 2012.”

We received your June 30, 2010, October 13, 2010, February 15, 2011, and March 1, 2011 labeling submissions to this application, and recommend the revisions listed below. Please note that our review of your submissions is ongoing, and we may have additional labeling recommendations for you.

Labeling

1. Change the established name under the statement of identity from [REDACTED] (b) (4) [REDACTED] to “Ibuprofen tablets 200 mg (provided as ibuprofen sodium 256 mg)” followed by the pharmacological categories on the outer carton principle display panels (PDPs) of all SKUs, on the side panel that can serve as an alternate PDP of the 120-count tablet SKU, and on the immediate containers of all SKUs per USP <1121> and 21 CFR 201.61(b).
2. “Caplet” is not a recognized dosage form designation in the CDER Data Standards manual. Define the term “Caplets” by placing a double asterisk (**) immediately following the word “Caplets” and define the “**” as “**capsule shaped tablets” on the PDPs of all SKUs.
3. Remove [REDACTED] (b) (4) [REDACTED] from the PDPs of all SKUs that bear this statement. The phrase may be misconstrued by consumers as a claim about the time to relief of symptoms.
4. To avoid medication errors, the front panel of the 2-count pouch needs to indicate that each tablet contains 200 mg ibuprofen and that 200 mg is not the total amount of

ibuprofen in the pouch. In accordance with 21 CFR 201.62(a), revise the declaration of net quantity of contents statement as follows: 2 coated tablets, 200 mg each.

5. Wherever the active ingredient is identified in the labeling (on all SKUs), change the active ingredient from [REDACTED] (b) (4) to “Ibuprofen 200 mg (provided as ibuprofen sodium 256 mg)” per USP <1121> and 21 CFR 201.66(c)(2).
6. Change the statement on the 8-count tablets immediate container (vial) from [REDACTED] (b) (4) to “Open here to view more product information” or another statement that does not imply the label contains complete Drug Facts.
7. Provision for the lot/control number (21 CFR 201.17) and expiration date (21 CFR 201.18) on the 2-count immediate container (pouch) must be provided.
8. Increase the prominence of the peel-back “Lift Here” labels on all the 8-count immediate container (vial) labels. This can be accomplished by increasing the size or changing the font color of the statement so it can be more easily seen. As currently presented, patients and healthcare professionals may not recognize that the required drug facts including important dosing information may be on a peel-back label adhered to the bottle.

When a new proprietary name is approved, labeling for all SKUs with the approved proprietary name must be submitted for our review prior to the action due date. Revise the presentation of the proprietary name, when determined and approved, to appear in a contiguous manner including the same font size, type, style, and color type. This presentation will emphasize the full name of the product. This presentation should be utilized regardless of the proprietary name that is used for this product.

If you have any questions, call LT James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Lesley-Anne Furlong, M.D., M.S.
Cross-Discipline Team Leader
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

LESLEYANNE A FURLONG
03/23/2011

MEMORANDUM OF MEETING MINUTES

MEETING DATE: March 10, 2011
TIME: 1:30 PM-2:30 PM EST
LOCATION: White Oak Conference Room 5322
DRUG NAME: Advil (b) (4) NDA 201803 RCM# 2011-29
TYPE OF MEETING: Teleconference with Pfizer

MEETING CHAIR: Todd Bridges

MEETING RECORDER: Cheryle Milburn, SRPM, OSE

FDA ATTENDEES: (Title and Office/Division)

Zachary Oleszczuk, Team Leader, DMEPA, OSE

Manizheh Siahpoushan, Safety Reviewer, DMEPA, OSE

EXTERNAL CONSTITUENT ATTENDEES:

Lauren Quinn, JD-Senior Director, Worldwide Regulatory Strategy

Suzanne Brabant-Director, Worldwide Regulatory Strategy

Heather Storms-Senior product Manager, US Marketing

Kevin Homler-Senior Director, Global Marketing

David Kellstein, Ph.D.- Senior Director, R&D, Clinical Research

John Schalago-Director, Worldwide Regulatory Strategy

Peter Ramsey, Ph.D.-Senior Director, R&D

Yael Gozin, Ph.D. -Manager, Worldwide Regulatory Strategy

BACKGROUND:

Because of the approaching OND ODUFA DMEPA contacted the Applicant to inform them that the name Advil (b) (4) would be found unacceptable.

MEETING OBJECTIVES:

- Discussion of Modifiers
- Discussion of Modifier (b) (4)
- Steps Forward

DISCUSSION POINTS:

- PDUFA is May 1, 2011- Hope to have a name approved by that date.
- Discussion of how the FDA evaluates proprietary names and modifiers
- 2006 IOM definition of modifiers
- FDA cannot think of an appropriate modifier for the active ingredient of salt.
- Advil recognizable as Ibuprofen; the best naming most likely another name to decrease the confusion—Pfizer does not accept this.

- FDA requested any information on testing of [REDACTED]^{(b) (4)} name—Pfizer did not research this.
- Suggestions from FDA: possible Pre-fix followed by Advil, or just the name Advil.

DECISIONS (AGREEMENTS) REACHED:

- None

UNRESOLVED ISSUES OR ISSUES REQUIRING FURTHER DISCUSSION:

- To close out name one of 2 things must take place
 1. withdraw [REDACTED]^{(b) (4)} name and submit a new request for proprietary name
 2. we will send out denial letter by April 3, 2011 to meet our April 4th PDUFA date.

ACTION ITEMS:

- Pfizer will discuss and let us know plan by tomorrow.

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/s/

CHERYE D MILBURN
05/09/2011

MEMORANDUM OF TELECON

DATE: March 3, 2011

APPLICATION NUMBER: NDA201803

BETWEEN:

Name: Yael Gozin, Ph.D.
Manager, Global Regulatory Affairs
Phone: 888-643-3083
Representing: Pfizer Consumer Healthcare

AND

Name: Joel Schiffenbauer, M.D., Melissa Furness, Lesley-Anne Furlong, Priscilla Callahan-Lyon, James Lee
Division of Nonprescription Clinical Evaluation, HFD-560

SUBJECT: Pfizer's Pediatric Waiver Request

The Deputy Division Director, Joel Schiffenbauer, informed the sponsor that their partial pediatric waiver request submitted in conjunction with their July 1, 2010 NDA application was denied, and that a pharmacokinetic bioequivalence study to evaluate a pediatric formulation of sodium ibuprofen dihydrate would be required to evaluate the safety and efficacy of the proposed ibuprofen salt formulation in the pediatric population.

James Lee, Regulatory Project Manager

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/s/

JAMES C LEE
03/22/2011

Lee, James C.

From: Lee, James C.
Sent: Friday, January 28, 2011 11:46 AM
To: 'Gozin, Yael'
Subject: Information Request: NDA 201803 Advil (b) (4)

Dear Dr. Gozin,

We are reviewing your NDA submission for NDA 201803 Advil (b) (4), and have the following information requests. Please respond in a timely manner to allow for adequate review time.

1. *Clinical*

Section 3.4 of Module 5.3.6.5 for NDA 201803 presents an analysis of "Acute Renal Failure in Pediatric Patients." The conclusion (section 3.4.4, page 20) states: Based on this review of the literature and case reports from the safety surveillance database, the RSI is being updated to advise consultation with a physician before ibuprofen use if the child may be in a hypovolemic state.

Section 3.7 of Module 5.3.6.5 presents an analysis of "Ibuprofen-Lithium Salts Drug Interaction." The conclusion (section 3.7.4, page 25) states: Based on this review, a drug-drug interaction between ibuprofen and lithium salts will be added to the ibuprofen CDS.

In contrast, the Executive Summary of this report states: No new major findings impacting the safety profile of ibuprofen were identified, and no additional action is warranted at this time. Additionally, the Overall Conclusion states: Review of the updated information from all four databases identified no new findings impacting the safety profile of ibuprofen. The limited information on ibuprofen sodium did not suggest any apparent differences in the safety profile of ibuprofen sodium compared to other ibuprofen formulations. As no new safety risks were identified and the safety profiles for ibuprofen and ibuprofen sodium do not appear different, the current ibuprofen Drug Facts labeling does not require change and is acceptable for use with ibuprofen sodium as proposed.

There seems to be a discrepancy. Please a) clarify what actions were taken and provide documentation and b) provide a rationale as to why or why not this will require a change of the OTC labeling.

2. *Labeling*

Provide labels for the (b) (4)-count store keeping units (SKUs). These sizes are currently listed in the chemistry portion of the application but labels are not provided in your NDA submission.

Do you plan to market the (b) (4)-count SKUs? If so, submit labeling for these sizes or tell us which labels represent these sizes.

3. *CMC*

Reference ID: 2897724

1/28/2011

We have received and reviewed your request to include the descriptor (b) (4) as part of your proper name. This proposal is not acceptable. Remove the word (b) (4) from all proposed labeling and replace with the USP approved descriptor "tablet". Provide clean copies of the revised labeling to your application.

If you have any questions, please contact me at your earliest convenience.

Best Regards,
James

LT James Lee, PharmD.
United States Public Health Service
Regulatory Project Manager
FDA-CDER-ODEIV
Division of Nonprescription Clinical Evaluation
10903 New Hampshire Avenue, Bldg. 22, Room 5471
Silver Spring, MD 20903
Tel: 301-796-5283 Fax: 301-796-9850
Email: james.lee4@fda.hhs.gov

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/s/

JAMES C LEE
01/28/2011

Liu, Youbang

From: Liu, Youbang
Sent: Friday, February 18, 2011 3:56 PM
To: 'Gozin, Yael'
Subject: NDA 201-803, Information Request

Dear Dr. Gozin,

We acknowledge receipt of your February 3, 2011 amendment containing a commitment to perform microbial limits testing on the final drug product. We also note that you declined to provide the test method or validation information. The specification currently references the entire USP/NF for the microbial enumeration methods. Please update the specification to include reference to USP chapters <61> and <62> for microbial limits testing.

Please acknowledge the receipt of this email and provide the time line of the amendment submission.

Regards,

Youbang Liu, Ph.D.
Regulatory Project Manager
ONDQA/OPS/CDER/FDA
Division III of New Drug Quality Assessment
10903 New Hampshire Avenue
Building 21, Room 2649
Silver Spring, MD 20993
Phone: (301) 796-1926
Fax: (301) 796-9748

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/s/

YOUBANG LIU
02/22/2011



NDA 201-803

INFORMATION REQUEST

Pfizer Consumer Healthcare
Attention: Yael Gozin, Ph.D.
Manager, Global Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Dr. Gozin:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ibuprofen sodium tablets, 256 mg.

We are reviewing the Chemistry, Manufacturing, and Control sections of your submission and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

Your proposed dissolution methodology is acceptable. However, your proposed dissolution specification needs to be $(b)(4)$ from $Q = \frac{(b)(4)}{(4)}\%$ at $\frac{(b)(4)}{(4)}$ min to $Q = \frac{(b)(4)}{(4)}\%$ at 15 min since $(b)(4)\%$ of Ibuprofen dissolved in 15 min.

Prior to approval, you should update your specification to reflect the newly recommended dissolution specification.

If you have any questions, call Youbang Liu, Regulatory Project Manager, at (301) 796-1926.

Sincerely yours,

{See appended electronic signature page}

Ali Al-Hakim, Ph.D.
Branch Chief, Branch VII
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

YOUBANG LIU
02/17/2011

ALI H AL HAKIM
02/17/2011

Tran-Zwanetz, Catherine

From: Tran-Zwanetz, Catherine
Sent: Thursday, January 20, 2011 4:41 PM
To: 'Gozin, Yael'
Cc: Liu, Youbang; Lee, James C.
Subject: RE: Pfizer Consumer: my email address

Hi Ms. Gozin,

Thank you for the email. Per our conversation here are the comments, we are requesting more information regarding pending NDA 201-803.

Please provide the following information or a reference to its location in the subject submission.

1. Your proposal to omit Microbial Limits testing is not adequately supported by data presented in this application. Provide the following information:
 - a. In-process test(s) that provide assurance of adequate microbial control during manufacture. These may include, (b) (4)
[REDACTED]
 - b. The maximum hold time for the (b) (4)
[REDACTED]

2. You may propose to omit finished product microbial limits testing for batch release and substitute in-process manufacturing controls, tests and acceptance criteria that provide assurance of the microbiological quality for each batch of your product as required in 21 CFR 211.165(a) and (b). Microbial limits testing as a release criteria can be eliminated but microbial limits testing should continue as part of the Stability Program with testing at the initial time point (at a minimum). A note indicating that microbial limits testing is performed only in the Stability Protocol should be added to the product's Specification Statement.

Please provide the information in a timely manner through the gateway.

Thank you for your time.

Cathy Tran-Zwanetz
Regulatory Project Manger
ONDQA

From: Gozin, Yael [mailto:Yael.Gozin@pfizer.com]
Sent: Thursday, January 20, 2011 2:52 PM
To: Tran-Zwanetz, Catherine
Subject: Pfizer Consumer: my email address

Dear Catharine,

Following our phone conversation, please send any questions and/or requests you have to this email address:

yael.gozin@pfizer.com

Thank you.

Kind Regards,
Yael

Reference ID: 2908399

2/22/2011

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/s/

CATHERINE A TRAN-ZWANETZ
02/22/2011

Lee, James C.

From: Lee, James C.
Sent: Friday, January 07, 2011 9:40 AM
To: 'Gozin, Yael'
Subject: NDA 201803 information request

Dear Dr. Gozin,

We are reviewing your NDA submitted July 1, 2010, and require the following additional information:

Provide the individual subject laboratory test results for both PK studies. We need to review individual results and the normal range for all the laboratory testing.

Please provide the requested information as soon as possible to allow for adequate review time.

If you have any questions, please feel free to contact me at your earliest convenience.

Best Regards,
James

LT James Lee, PharmD.
United States Public Health Service
Regulatory Project Manager
FDA-CDER-ODEIV
Division of Nonprescription Clinical Evaluation
10903 New Hampshire Avenue, Bldg. 22, Room 5471
Silver Spring, MD 20903
Tel: 301-796-5283 Fax: 301-796-9850
Email: james.lee4@fda.hhs.gov

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/s/

JAMES C LEE
01/10/2011



NDA 201803

INFORMATION REQUEST

Pfizer Consumer Healthcare
Attention: Yael Gozin, Ph.D.
Manager, Global Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Dr. Gozin:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ibuprofen sodium tablets, 256 mg.

We are reviewing the labeling, and chemistry, manufacturing, and control sections of your submission and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

Chemistry, Manufacturing, and Control:

Drug Substance:

1. Provide a letter of authorization for DMF (b) (4) (ibuprofen sodium) to cross reference DMF (b) (4)
2. Update the NDA when the USAN name is approved for your ibuprofen sodium drug product.

Drug Product:

3. The descriptor (b) (4) is not an acceptable dosage form designation for a tablet. It is not listed in the FDA Data Standards Manual of approved dosage forms.
4. Provide technical illustrations and specifications for the proposed tablet shapes (b) (4)
5. Provide a discussion of the factors which influenced the selection of the final film-coating formulation for the drug product.
6. Provide copies of the representative supplier's Certificates of Analysis (CoAs) for each excipient used in the manufacture of your ibuprofen sodium tablet.
7. Provide a letter of authorization to access DMF (b) (4) and make sure that the DMF holder updates the DMF to reflect this authorization.
8. Provide a scientific rationale as to why moisture content and friability need not be included as part of the lot release and stability specifications, or include specifications for these quality parameters for lot release and stability.

9. Provide representative drawings for all immediate container (bottle) configurations to be used with the drug product.
10. Provide a table demonstrating that critical physical properties of all intended immediate containers (bottles) [e.g. height, diameter, volume, surface area] are proportional.
11. Provide a justification/ rational as to why a coil is not required for tablets packed into the bottle container/ closure system.
12. Provide data indicating the similarity or difference in the volumes of the (b) (4) tablets (b) (4).
13. Provide side-by-side presentations of statistical, graphical analysis of stability data for (b) (4) tablet presentations (b) (4) in all immediate containers (bottles, pouches and vials). Include statistical trend analysis of the available real-time stability data in the provided graphical trend analysis profiles to support your proposed dating period.
14. Provide any additional stability data to support your proposed expiry dating.

Method Validation:

15. Indicate why the exhibit batches are not consecutively numbered.

Labeling:

1. Submit "Drug Facts" font specifications for all SKU labels (please refer to 21 CFR 201.66(d)).
2. Provide labels for the (b) (4)-count store keeping units (SKUs). These sizes are currently listed in the chemistry portion of the application but labels are not provided in your NDA submission.
3. The following are comments to our preliminary review of the submitted labeling. Further comments will be conveyed at a later date:
 - a. Revise the proposed labeling to state "ibuprofen sodium 256 mg, equivalent to ibuprofen 200 mg" on both the Principle Display Panel and the Active ingredient section of Drug Facts.
 - b. Add the bolded subheading, "**Stomach bleeding warning:**" to the immediate container labels for all SKUs in accordance with 21 CFR 201.326(a)(2)(iii)(A).

Biopharmaceutics:

1. Provide the dissolution development report for the proposed dissolution methodology. If you have already done so, provide the location of the data in your NDA submission (e.g. module, section, volume, and page numbers).
2. Provide a justification for the selected final dissolution methodology and proposed specifications.

If you have any questions, call James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Melissa Hancock Furness
Chief, Project Management Staff
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

MELISSA H FURNESS
12/15/2010



NDA 201-803

GENERAL ADVICE

Pfizer Consumer Healthcare
Attention: Yael Gozin
Manager, Global Reg. Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Mr. Gozin:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil® (b) (4) (sodium ibuprofen (b) (4)) Tablet, (b) (4) 256 mg.

We have reviewed your proposal for the established name for your product. Based on the available data and guidance we recommend the following established name, "ibuprofen sodium". This name will need to be approved through USAN.

Accordingly, the following revisions will need to be noted in the NDA:

(b) (4)

The tablets would be labeled as containing:

ibuprofen sodium 228 mg, equivalent to ibuprofen 200 mg.

If you have any questions, call Youbang Liu, Regulatory Project Manager, at (301) 796-1926.

Sincerely yours,

{See appended electronic signature page}

Ali Al-Hakim, Ph.D.
Branch Chief, Branch VII
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

ALI H AL HAKIM
10/13/2010



NDA 201803

**PROPRIETARY NAME REQUEST
UNACCEPTABLE**

Pfizer Consumer Healthcare
5 Giralda Farms
Madison, New Jersey 07940

ATTENTION: Yael Gozin, Ph.D.
Manager, Global Regulatory Affairs

Dear Dr. Gozin:

Please refer to your New Drug Application (NDA) dated June 30, 2010, received July 1, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sodium Ibuprofen (b)(4) Tablets, 256 mg.

We also refer to your July 12, 2010, correspondence, received July 12, 2010, requesting review of your proposed proprietary name, Advil (b)(4). We have completed our review of this proposed proprietary name and have concluded that this name is unacceptable for the following reasons. The proposed name 'Advil (b)(4)' is misleading pursuant to 21 CFR 201.10(c)(3) which states:

The employment of a fanciful proprietary name for a drug or ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition when, in fact the drug or ingredient is a common substance the limitation of which are readily recognized when the drug or ingredient is listed by its established name.

The proposed proprietary name, Advil (b)(4), implies superiority over similar products. Specifically, "Advil (b)(4)" contains the word "(b)(4)", which can be defined as (b)(4)

(b)(4). The drug product's proposed indication is for the temporary relief of minor aches and pains and for the reduction of fever. Therefore, the proposed proprietary name misleadingly implies that the drug offers a clinical improvement over existing therapies by (b)(4) the efficacy of similar products. In the absence of substantial evidence to support the claim that the product provides pain and fever relief beyond that of other products, the proposed proprietary name is misleading.

We note that you have not proposed an alternate proprietary name for review. If you intend to have a proprietary name for this product, we recommend that you submit a new request for a proposed proprietary name review. (See the draft Guidance for Industry, *Complete Submission for the Evaluation of Proprietary Names*, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm121568.htm> and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012”.)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Janet L. Anderson, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-0675. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager James Lee at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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/s/

CAROL A HOLQUIST
10/08/2010



NDA 201803

NDA ACKNOWLEDGMENT

Pfizer Consumer Healthcare
Attention: Yael Gozin, Ph.D.
Manager, Global Regulatory Affairs
5 Giralda Farms, Madison, NJ 07940

Dear Dr. Gozin:

We have received your New Drug Application (NDA) submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product: Advil ^{(b)(4)} (256 mg sodium ibuprofen ^{(b)(4)}) tablets

Date of Application: July 1, 2010

Date of Receipt: July 1, 2010

Our Reference Number: NDA 201803

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 August 30, 2010 accordance with 21 CFR 314.101(a).

The NDA number provided above should be cited 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 Drug Evaluation IV
Division of Nonprescription Clinical Evaluation
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is

NDA 201803

Page 2

shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, please see

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm>

If you have any questions, call James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Neel Patel, Pharm.D.
Regulatory Project Manager
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201803	ORIG-1	PFIZER CONSUMER HEALTHCARE DIV WARNER LAMBERT CO	Sodium Ibuprofen, 256 mg (ibuprofen 200 mg)

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/s/

NEEL PATEL
07/08/2010