CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 19012/S-052

Name: Motrin® IB (ibuprofen) Tablets

Sponsor: McNeil Consumer Healthcare

Approval Date: March 11, 2014

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of an analytical testing site for the drug product.

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CONTENTS

Reviews / Information Included in this Review

Approval Letter	**X**
Approvable Letter	
Labeling	
Division Director's Memo	
Labeling Review(s)	
Medical Review(s)	
Chemistry Review(s)	**X**
Environmental Assessment	
Pharmacology / Toxicology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology & Biopharmaceutics Review(s)	
Other Review(s)	
Administrative and Correspondence Documents	

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19012/S-052

APPROVAL LETTER

McNeil Consumer Healthcare
Attention: Samuel A. Herald, M.S., Associate Director
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Mr. Herald:

Please refer to your Supplemental New Drug Application (sNDA) dated September 11, 2013, received September 11, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MOTRIN® IB (ibuprofen) Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of (b) (4), in (b) (4), as an analytical testing site (Micro) for the drug product.

We have completed our review of this supplemental new drug application. This supplement is approved.

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 Rebecca McKnight, Regulatory Project Manager, at (301) 796-1765.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Branch Chief, Branch IX
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

/s/

RAMESH RAGHAVACHARI
03/11/2014

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APPLICATION NUMBER:

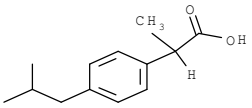
NDA 19012/S-052

CHEMISTRY REVIEWS

chemistry review #1	1. Division ONDQA	2. NDA & Suppl. Number 19-012/SCM-052
3. Name and Address of Applicant McNeil Consumer Healthcare Attention: Samuel A. Herald, M.S., Associate Director 7050 Camp Hill Road Fort Washington, PA 19034-2299		**4. DATE** **Submission** **PDUFA** 9/11/13 3/11/14
5. Name of Drug: MOTRIN® IB	**6. Nonproprietary Name:** Ibuprofen tablets	
7. Supplement, CBE-30, Provides for: A new packaging site, (b) (4)		**8. Amendment Date**
9. Pharmacological Category	**10. How Dispensed:** Rx	**11. Related Documents**
12. Dosage Form: Tablets	**13. Potency(ies):** 200 mg.	

14. Chemical Name: : Ibuprofen, (*RS*)-2-(4-(2-methylpropyl)phenyl)propanoic acid

Structure:



Molecular Formular $C_{13}H_{18}O_2$

Molecular Weight 206.28

15. Comments:

1. The facility, (b) (4) has been inspected and was found acceptable. A copy of the EER is attached.
2. The test methods used at (b) (4) are approved in the NDA.
3. There are no post-approval commitments relating to the test methods.
4. (b) (4) has the capability to perform the testing.

16. Conclusions and Recommendations: Recommend Approval.

17. Name: Review Chemist Signature Date
Bart Ho

Branch Chief Signature Date
Ramesh Raghavachari, Ph.D.

Doc ID: 19012SCM052 Test Lab McNeil

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application:	NDA 19012/052	**Sponsor:**	MCNEIL CONS
Org. Code:	560		7050 CAMP HILL RD
Priority:	5S		FORT WASHINGTON, PA 19034
Stamp Date:	11-SEP-2013	**Brand Name:**	MOTRIN MIGRAINE PAIN
PDUFA Date:	11-MAR-2014	**Estab. Name:**	
Action Goal:		**Generic Name:**	IBUPROFEN
District Goal:	04-FEB-2014	**Product Number; Dosage Form; Ingredient; Strengths**	001; TABLET; IBUPROFEN; 200MG 003; TABLET; IBUPROFEN; 200MG 002; TABLET; IBUPROFEN; 200MG 004; TABLET; IBUPROFEN; 200MG

FDA Contacts:	S. DE	Prod Qual Reviewer	3017961664
	R. MCKNIGHT	Product Quality PM	3017961765

Overall Recommendation:	ACCEPTABLE	on 04-NOV-2013	by T. SHARP	()	3017963208
	PENDING	on 04-NOV-2013	by EES_PROD		

Establishment: **CFN:** (b) (4) **FEI:** (b) (4)

(b) (4)

(b) (4)

DMF No: **AADA:**

Responsibilities:	FINISHED DOSAGE OTHER TESTER
Profile:	CONTROL TESTING LABORATORY
OAI Status:	NONE
Last Milestone:	OC RECOMMENDATION
Milestone Date:	04-NOV-2013
Decision:	ACCEPTABLE
Reason:	BASED ON PROFILE

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

/s/

BARTHOLOME C HO
03/07/2014

RAMESH RAGHAVACHARI
03/07/2014