

NDA 18-060  
S-055



NDA 18-060/S-055

G&W Laboratories, Inc.  
Attention: Norman C. Gebelhoff  
Director, Quality Assurance/Regulatory Compliance  
111 Coolidge Street  
South Plainfield, New Jersey 07080-3895

Dear Mr. Gebelhoff:

We acknowledge your supplemental new drug application dated March 2, 1994, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ACEPHEN (acetaminophen suppositories, USP). The supplemental application provides for final printed labeling for the individual foil wrapper, labels and boxes.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on March 2, 1994. Accordingly, this supplemental application is approved effective on the date of this letter.

Please note that we recommend the storage statement be revised to include the temperature in centigrade and to provide a temperature range (i.e., Store at 35°-80°F (2°-27° C)).

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, please contact Sandra N. Cook, Project Manager, at (301) 827-2090.

Sincerely,

WAC 3/31/97

Wiley A. Chambers, M.D.  
Acting Director  
Division of Anti-Inflammatory, Analgesic, and  
Ophthalmic Drug Products, HFD-550  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

NDA 18-060/S-055

Page 2

cc: NDA 18-060  
HFD-550 (with labeling)  
HFD-560 (with labeling)  
HFD-105  
HFD-550/CSO/S.Cook  
HFD-550/SPMS/LoBianco  
DISTRICT OFFICE  
HF-2/Medwatch (with labeling)  
HFD-92/DDM-DIAB (with labeling)  
HFD-40/DDMAC (with labeling)  
HFD-613/OGD (with labeling)  
HFD-735/DPE (with labeling)  
HFI-20/Press Office (with labeling)

Drafted by: /LoBianco March 31, 1997/18060ap.s55

Initialed by: *SL* 3/31/97

final: chambers March 31, 1997

APPROVAL (AP)

Labeling: OF SUPPL

NDA No: 12060 Rec'd. MAR 7 1981

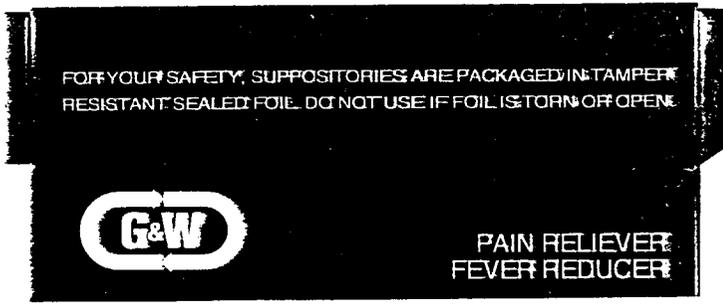
Reviewed by: [Signature]



Aspirin Free

**Acephen** <sup>TM</sup> BRAND

**Acetaminophen Suppositories USP**  
**(Pediatric) 120 mg**



Aspirin Free

**Acephen** <sup>TM</sup> BRAND

**Acetaminophen**  
**Suppositories USP**  
**(Pediatric) 120 mg**

12 Rectal Suppositories



10-11811GW 3

**Acephen** <sup>TM</sup>  
BRAND



**Acetaminophen**  
**Suppositories USP (Pediatric) 120 mg**

Indications: For the temporary relief of fever, minor aches, pains and headaches.

Each suppository contains: Acetaminophen 120 mg.

Dosage: Children (3-6 years) – Insert one suppository into rectum every 4-6 hours. No more than a total of 6 suppositories may be administered in any 24 hour period.

Children (under 3) consult a physician.

Directions: For rectal administration. Remove foil wrapper and insert suppository well up into rectum.

**Store below 80° F or refrigerate.**

Warning: Severe or recurrent pain or high or continued fever may be indicative of serious illness. If fever persists for more than 3 days ( 72 hours), or recurs, consult your physician. Do not use consistently for more than 5 days except on the advice of a physician.

**Keep this and all drugs out of the reach of children.**

**In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.**



Laboratories

South Plainfield, N.J. 07080



Labeling: OK

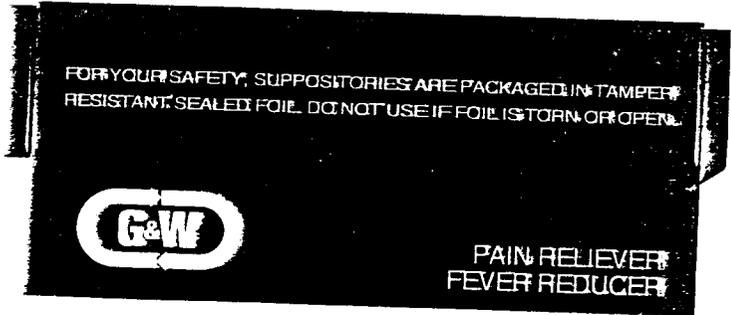
NDA No: 18060 Rec'd. 1/12

Reviewed by: [Signature]



**Acephephen** <sup>TM</sup> BRAND

**Acetaminophen Suppositories USP**  
**(Pediatric) 120 mg**



**PAIN RELIEVER**  
**FEVER REDUCER**

Aspirin Free

**Acephephen** <sup>TM</sup> BRAND  
**Acetaminophen**  
**Suppositories USP**  
**(Pediatric) 120 mg**  
12 Rectal Suppositories



10-11811GW 3

Labeling: 18-060

NDA No: 18-060 Rev'd.

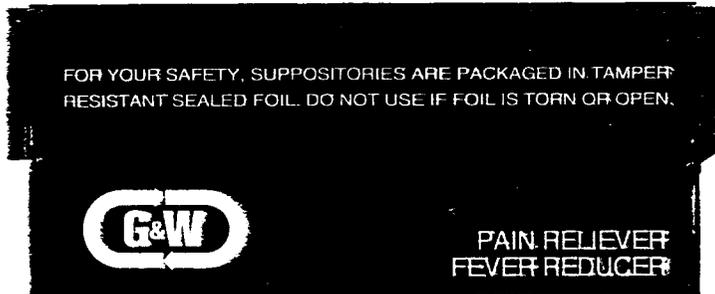
Reviewed by: W. J. ...



Aspirin Free

**Acephen** <sup>TM</sup> BRAND

**Acetaminophen Suppositories USP  
(Pediatric) 120 mg**



Aspirin Free

**Acephen** <sup>TM</sup> BRAND

**Acetaminophen  
Suppositories USP  
(Pediatric) 120 mg**

6 Rectal Suppositories



**APPROVED**

10-11866GW 1

**Acephen** <sup>TM</sup>  
EPMAND



**Acetaminophen**  
**Suppositories USP (Pediatric) 120 mg**

Indications: For the temporary relief of fever, minor aches, pains and headaches.

Each suppository contains: Acetaminophen 120 mg.

Dosage: Children (3-6 years) – Insert one suppository into rectum every 4-6 hours. No more than a total of 6 suppositories may be administered in any 24 hour period.

Children (under 3) consult a physician.

Directions: For rectal administration. Remove foil wrapper and insert suppository well up into rectum.

**Store below 80° F or refrigerate.**

Warning: Severe or recurrent pain or high or continued fever may be indicative of serious illness. If fever persists for more than 3 days ( 72 hours), or recurs, consult your physician. Do not use consistently for more than 5 days except on the advice of a physician.

**Keep this and all drugs out of the reach of children.**  
**In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.**



Laboratories  
South Plainfield, N. J. 07080



Labeling: OK 1/11/12

NDA No: 12566 Re'd, \_\_\_\_\_

Reviewed by: [Signature]

**APPROVED**

FOR YOUR SAFETY, SUPPOSITORIES ARE PACKAGED IN TAMPER-RESISTANT  
SEALED FOIL. DO NOT USE IF SEAL IS TORN OR OPEN.

NDC 0713-0118-12



Acetaminophen Suppositories USP  
(pediatric)

Pain Reliever  
Fever Reducer  
**ASPIRIN FREE**

12 Rectal Suppositories

Acetaminophen Suppositories USP

10-11812GW7

**INDICATIONS:** For the temporary relief of fever, minor aches, pains and headaches.

Each suppository contains: Acetaminophen 120 mg.

**Dosage:** Children (3-6 years ) - Insert one suppository into rectum every 4-6 hours. No more than a total of 6 suppositories may be administered in any 24 hour period. Children (under 3) consult a physician.

**Directions:** For rectal administration. Remove foil wrapper and insert suppository well up into rectum.

**Store below 80° F or refrigerate.**

**WARNING:** Severe or recurrent pain or high or continued fever may be indicative of serious illness. If fever persists for more than 3 days (72 hours), or recurs consult your physician. Do not use consistently for more than 5 days except on the advice of a physician.

**Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.**



**G&W** Laboratories, Inc. South Plainfield, NJ 07080



6671  
06106  
9

Labeling: \_\_\_\_\_  
NDA No: 18-060 Rec'd. MAR 7 199  
Reviewed by: \_\_\_\_\_

**INDICATIONS:** For the temporary relief of fever, minor aches, pains and headaches.  
Each suppository contains: 120 mg  
Acetaminophen  
**DOSAGE:** Children - (3-6 years) - Insert one suppository into rectum every 4-6 hours. No more than a total of 6 suppositories may be administered in any 24 hour period. Children (under 3) - consult a physician.  
**Directions:** For rectal administration. Remove foil wrapper and insert suppository well up into rectum. Store below 80°F or refrigerate.

NDC 0713-0118-10  
ASPIRIN FREE

**ACEPHEN™**  
ACETAMINOPHEN  
SUPPOSITORIES  
USP (Pediatric)  
120 mg

PAIN RELIEVER-  
FEVER REDUCER  
1000 RECTAL SUPPOSITORIES

**WARNING:** Severe or recurrent pain or high or continued fever may be indicative of serious illness. If fever persists for more than 3 days (72 hours), or recurs, consult your physician. Do not use consistently for more than 5 days except on the advice of a physician.  
Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.  
**FOR YOUR SAFETY, SUPPOSITORIES ARE PACKAGED IN TAMPER-RESISTANT SEALED FOIL. DO NOT USE IF FOIL IS TORN OR OPEN.**



12-11810GW1

G\*W Laboratories, Inc.  
South Plainfield, N.J. 07080



Labeling: \_\_\_\_\_

NDA No: 18-060 Rec'd. \_\_\_\_\_

Reviewed by: \_\_\_\_\_

**INDICATIONS:** For the temporary relief of fever, minor aches, pains and headaches.

Each suppository contains: Acetaminophen 120 mg

**DOSAGE:** Children - (3-6 years) - Insert one suppository into rectum every 4-6 hours. No more than a total of 6 suppositories may be administered in any 24 hour period. Children (under 3) - consult a physician.

**Directions:** For rectal administration. Remove foil wrapper and insert suppository well up into rectum. Store below 80°F or refrigerate.

NDC 0713-0118-01  
ASPIRIN FREE

**ACEPHEN™**  
ACETAMINOPHEN  
SUPPOSITORIES  
USP (Pediatric)  
120 mg

PAIN RELIEVER-  
FEVER REDUCER  
100 RECTAL SUPPOSITORIES

**WARNING:** Severe or recurrent pain or high or continued fever may be indicative of serious illness. If fever persists for more than 3 days (72 hours), or recurs, consult your physician. Do not use consistently for more than 5 days except on the advice of a physician.

Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

**FOR YOUR SAFETY, SUPPOSITORIES ARE PACKAGED IN TAMPER-RESISTANT SEALED FOIL. DO NOT USE IF FOIL IS TORN OR OPEN.**



**G•W** Laboratories, Inc.  
South Plainfield, N.J. 07080

Labeling: \_\_\_\_\_

NDA No: 18-060 Re'd. \_\_\_\_\_

Reviewed by: \_\_\_\_\_

**INDICATIONS:** For the temporary relief of fever, minor aches, pains and headaches.

Each suppository contains: Acetaminophen 120mg

**DOSAGE:** Children (3-6 years)- Insert one suppository into rectum every 4-6 hours. No more than a total of 6 suppositories may be administered in any 24 hour period. Children (under 3)- consult a physician.

**Directions:** For rectal administration. Remove foil wrapper and insert suppository well up into rectum.

Store below 80°F or refrigerate.

12-11850GW4



0713-0118-50

NDC 0713-0118-50  
ASPIRIN FREE

**ACEPHEN™**  
ACETAMINOPHEN  
SUPPOSITORIES  
USP (Pediatric)

120 mg

**PAIN RELIEVER-  
FEVER REDUCER**  
**50 RECTAL  
SUPPOSITORIES**

**WARNING:** Severe or recurrent pain or high or continued fever may be indicative of serious illness. If fever persists for more than 3 days (72 hours), or recurs, consult your physician. Do not use consistently for more than 5 days except on the advice of a physician.

Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

FOR YOUR SAFETY, SUPPOSITORIES ARE PACKAGED IN TAMPER-RESISTANT SEALED FOIL. DO NOT USE IF FOIL IS TORN OR OPEN.



**G&W** LABORATORIES, INC.  
South Plainfield, N.J. 07080

Labeling Review of NDA 18-060/S-055

NDA 18-060/S-055

Submission dates: 3/2/94  
Review date: 3/31/97

Applicant: G& W Laboratories, Inc.  
111 Coolidge Street  
South Plainfield, NJ 07080-3895  
908-753-2000

Applicant's Representative: Norman C. Gebeloff  
Director, Quality Assurance/Regulatory Compliance

Drug: ACEPHEN (acetaminophen suppositories, USP)

Pharmacologic Category: Pain reliever/ fever reducer

Submitted: This supplement was submitted under 21 CFR 314.70 (c)(2), as "Changes Being Effected". This supplement provides for final printed labeling for the individual foil wrapper, labels and boxes, and conforms to the approved labeling in G&W Labs, Inc., ANDA 72-218.

Related Reviews: See Chemistry/Manufacturing Review dated 7/19/94.

**Additional Statements:** Storage Statement: Store below 80°F or refrigerate.

**Reviewer's Comments:** *The storage statement should be revised to include the temperature in centigrade and to provide a temperature range (i.e., Store at 35-80°F (2°-27° C)).*

**Recommendation:**

This supplement is approvable and the additional comments should be given as recommendations.

m/d

Wiley A. Chambers, M.D.

cc: Orig NDA 18-060  
HFD-550  
HFD-560  
HFD-550/Cook  
HFD-550/Chambers



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NDA 18-060

March 9, 1994

G & W Laboratories, Inc.  
111 Coolidge Street  
South Plainfield, New Jersey 07080

Attention: Norman C. Gebeloff, Director  
Quality Assurance/Regulatory Compliance

Dear Mr. Gebeloff

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Acetaminophen Suppositories, USP 120mg

NDA Number: 18-060

Supplement Number: S-055

Date of Supplement: March 2, 1994

Date of Receipt: March 7, 1994

Should you have any questions, please contact

Sandy Barnes  
Project Manager  
(301) 443-3741

Sincerely yours,

For Project Manager  
Pilot Drug Evaluation Staff,  
HFD-007  
Center for Drug Evaluation and  
Research



LABORATORIES, INC.

111 Cocke Street, South Plainfield, New Jersey 07080-3895 908-753-2000 FAX 908-753-9264

ORIGINAL

NDA NO. 18-060 DTD. NO. 050

NDA SUPPL FOR SCR

March 2, 1994

Director  
Pilot Drug Evaluation Staff, HFD-007  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Reference: NDA 18-060  
Acetaminophen Suppositories, USP

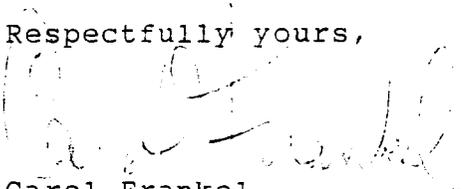
SPECIAL SUPPLEMENT CHANGES BEING EFFECTED

Gentlemen:

Submitting herewith to the above referenced NDA are 12 copies of final printed labeling which include the individual foil wrapper, labels (50,100,1000 count) and boxes (6 and 12 count) which conform with the approved labeling in the G & W Labs, Inc. ANDA 72-218 for the 120mg. potency suppository. In addition the phrase "Aspirin Free" has been included to bring this labeling into line with other acetaminophen marketed products.

Thank you for your kind cooperation in including this information in the file of reference.

Respectfully yours,

  
Carol Frankel  
Consultant in Regulatory Affairs  
333 East 57 Street  
New York, N.Y. 10022  
(212) 755-2339

