CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75588

CHEMISTRY REVIEW(S)

ANDA APPROVAL SUMMARY

ANDA:	CHEMIST:	DATE:
75-588	Gil Kang	March 11, 2002

DRUG PRODUCT:

Ibuprofen and Pseudoephedrine HCl Tablets, USP

FIRM:

Pharmaceutical Formulations, Inc.

DOSAGE FORM:	STRENGTH:
Tablets (Oval capsule-shaped tablets and round tablets)	Ibuprofen 200 mg/Pseudoephedrine HCl 30 mg

cGMP:

Acceptable on 31-MAY-2000

BIO:

Bioequivalence was reviewed by S.P.Shrivastava and found acceptable on 26-MAY-1999.

VALIDATION - *(Description of dosage form same as firm's):*

USP product

STABILITY:

The firm has provided 3 months accelerated and 24 months room temperature stability data for Ibuprofen and Pseudoephedrine HCl Tablets, USP (round and oval) stored in unit dose blister pack, and both stability results support an expiration period of 24 months.

The firm has also provided 3 months accelerated and room temperature stability data for Ibuprofen and Pseudoephedrine HCl Tablets, USP stored in bulk package and the result of both stability studies demonstrated that the drug product in bulk container are satisfactory up to 3 months.

LABELING:

Labeling was reviewed by J. Barlow and found satisfactory on 04-DEC-2001.

STERILIZATION VALIDATION *(If applicable)*:

N/A

SIZE OF BIO BATCH *(Firm's source of NDS ok?)*:

The sizes of bio-batches are oval tablets kg, Lot No. H79293/22453F).

The drug substances, Ibuprofen USP and Pseudoephedrine Hydrochloride USP are manufactured by

SIZE OF STABILITY BATCHES *(If different from bio batch, were they manufactured via the same process?):*

N/A

ROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME?:

Manufacturing process is same.

Signature of chemist:	Signature of supervisor:
/S/ 3/11/02	3/12/02

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Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Abbreviated New Drug Application Review

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1. CHEMISTRY REVIEW NO.: 1

2. ANDA #: 75-588

3. NAME AND ADDRESS OF APPLICANT:

   Pharmaceutical Formulation, Inc.
   460 Plainfield Avenue
   Edison, New Jersey 08818

4. LEGAL BASIS FOR SUBMISSION:

   Reference-Listed Drug: Advil Cold & Sinus

   Whitehall Laboratories
   Application No. N19771 001

   Strength: Ibuprofen (200 mg)
   Pseudoephedrine HCl (30 mg)

   Paragraph IV certification (the claims of reexamination) to the patent No. 4,552,899 (expiring on November 12, 2002 with a pediatric extension to May 12, 2003) is provided in the amendment dated 03-04-99.
   On April 19, 1999, PFI submitted patent amendment regarding the notice sent to each person identified under 21 CFR 314.95(a).

   Exclusivity: Expired on 9-19-1992

5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME: Ibuprofen Cold & Sinus

7. NONPROPRIETARY NAME:
   Ibuprofen/Pseudoephdrine Hydrochloride tablets USP

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

02-19-1999	Date of ANDA submission.
03-04-1999	Revised patent certification and Bio waiver
03-09-1999	Acknowledge letter by Agency
04-19-1999	Paragraph IV patent certification notification
04-26-1999	Bioequivalence telephone amendment
05-21-1999	Minor labeling amendment

05-28-1999 Patent amendment (expiration of 45-day period)

10. PHARMACOLOGICAL CATEGORY:
Ibuprofen: Anti-inflammatory
Pseudoephedrine Hydrochloride: Adrenergic (vasoconstrictor).

For temporary relief of symptoms associated with the common cold, sinusitis or flu including nasal congestion, headache, fever, body aches, and pains.

11. Rx or OTC: OTC

12. RELATED IND/NDA/DMF(s):

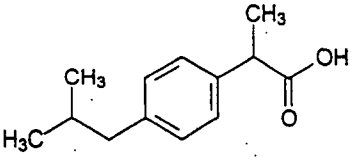
DMF#	TYPE	SUBJECT	HOLDER
	II	Ibuprofen	
	II	Pseudoephedrine	
	III	PVC sheet	
	III	Blister pack	
	III	Desiccant	
	III	Resin	

13. DOSAGE FORM: Tablets

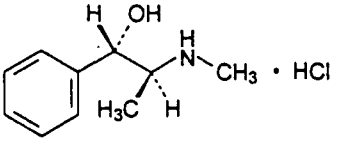
14. POTENCIES: Ibuprofen: 200 mg / Pseudoephedrine HCl: 30 mg

15. CHEMICAL NAME AND STRUCTURE:

Ibuprofen: Benzeneacetic acid, α-methyl-4-(2-methylpropyl),(±)-. $C_{13}H_{18}O_2$. Mol. Wt. 206.29



Pseudoephedrine Hydrochloride: Benzenemethanol, α-[1-(methylamino)ethyl]-, [*S*-(*R**,*R**)]-, hydrochloride. $C_{10}H_{15}NO \cdot HCl$. Mol. Wt. 201.7.



16. RECORDS AND REPORTS: None

17. COMMENTS: Comments are described in the review item No. 38.

18. CONCLUSIONS AND RECOMMENDATIONS:

The application is not approvable (Major).

19. REVIEWER: Gil Kang DATE COMPLETED: 8-31-1999

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Chem Review #1

38. Chemistry Comments to be Provided to the Applicant

AADA/ANDA: 75-588
APPLICANT: Pharmaceutical Formulation
DRUG PRODUCT: Ibuprofen/Pseudoephedrine Hydrochloride Tablets USP 200 mg/30 mg

The deficiencies presented below represent MAJOR deficiencies

A. Deficiencies:

1. DMF No.( ) for Pseudoephedrine HCl is currently inadequate. The holder has been notified.

2. You have stated that the tests and specifications (OVI and median particle size) for Ibuprofen drug substance meet USP 23 requirements on page 1355. Please clarify how this relates to particle size test. Also, you need a vendor validation program to rely on the vendor's certificate of analysis. Please correct the statement and provide your particle size test method and results.

3. You have stated that the tests and specifications for Pseudoephedrine HCl drug substance meet USP 23 requirements and they are based on the supplier's COA on page 1374. Please explain for which tests this statement is intended. Also, you have used an outside testing firm ( ) for the OVI test, but the firm is not listed in the section of outside firms (page 1487). Please correct and provide a CGMP certification letter from ( )

4. You have set retest dates for inactive ingredients, Silicon Dioxide, Stearic Acid and Carnauba wax at 35 months. We recommend a 24 months retest period for inactive ingredients.

5. Please demonstrate that the maximum daily dose of 5 mg of iron per day cannot be exceeded. The limit of elemental iron per day is 5 mg according to 21 CFR 73.1200(c).

6. The amount of Microcrystalline Cellulose in the composition on page 1345 (mg/tablet) is

different from the amount in the blank batch record (pp. 1494-1500).

7. The resin for bulk bag is described as high density polyethylene liner on page 1683, but as low density polyethylene liner on page 1687. Please clarify. In addition, please provide DMF authorization letter for (resin and the DMF information for

8. You have committed to perform (on the first three validation batches of Ibuprofen/Pseudoephedrine HCl Tablets USP as a part of process validation. Please revise your commitment to include the (as a part of in-process controls for the commercial production batches. We recommend acceptance criteria as % (mean of individual test results) with a relative standard deviation of %. In addition, we do not recommend the second stage test when the first stage test fails.

9. The result of on Ibuprofen/Pseudoephedrine HCl Tablets (round) are significantly variable (%). Please explain.

10. The net weight (kg) in on page 1519 is below the lowest limit kg). Please explain. Also, you have explained that the low yield is due to the numerous samples taken by R & D and validation prior to compression (pp. 1519). Please provide detailed information on how the kg of was used.

11. Please provide tests and specifications for "water" and "description" of the finished drug product and include these tests in the stability protocol.

12. Please justify the "any other identified impurity (NMT( )" and "total impurity limits (NMT

%)" for Ibuprofen and Pseudoephedrine HCl of the finished product.

13. The USP 23 specifies that the tailing factors for the individual peaks of Ibuprofen tablets are not more than Please include this specification in the analytical method for Ibuprofen USP.

14. The assay result of Pseudoephdrine HCl accelerated stability data shows downward trend up to % , but none of the impurities were detected in the accelerated stability study. Please explain. Also, please provide all available controlled room temperature stability data.

15. Please tighten the limits for any other identified impurity, and total impurities for Ibuprofen and Pseudoephedrine HCl in the stability protocol based on the actual stability data.

B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

1. The firms referenced in the application relative to the manufacturing and testing of the product must be in compliance with cGMPs at the time of approval.

2. USP methods for the drug substance and product are the regulatory methods and prevail in the event of dispute.

Sincerely yours,

/S/

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Abbreviated New Drug Application Review

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1. CHEMISTRY REVIEW NO.: 2

2. ANDA #: 75-588

3. NAME AND ADDRESS OF APPLICANT:
Pharmaceutical Formulations, Inc.
460 Plainfield Avenue
Edison, New Jersey 08818

4. LEGAL BASIS FOR SUBMISSION:

Reference-Listed Drug: Advil Cold & Sinus

Whitehall Laboratories
Application No. N19771 001

Strength: Ibuprofen (200 mg)
Pseudoephedrine HCl (30 mg)

Paragraph IV certification to the patent No. 4,552,899 (expiring on November 12, 2002 with a pediatric extension to May 12, 2003) is provided in the amendment dated 03-04-99.

Exclusivity: Expired on 9-19-1992

5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME: Ibuprofen Cold & Sinus

7. NONPROPRIETARY NAME:
Ibuprofen/Pseudoephdrine Hydrochloride tablets USP

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

02-19-1999	Date of ANDA submission.
03-04-1999	Revised patent certification and Bio waiver
03-09-1999	Acknowledge letter by Agency
04-19-1999	Paragraph IV patent certification notification
04-26-1999	Bioequivalence telephone amendment
05-21-1999	Minor labeling amendment
05-28-1999	Patent amendment (expiration of 45-day period)
10-12-1999	Deficiency letter based on review #1 (Major)
12-02-1999	Response to deficiency letter
03-17-2000	Labeling amendment

10. PHARMACOLOGICAL CATEGORY:
Ibuprofen: Anti-inflammatory
Pseudoephedrine Hydrochloride: Adrenergic (vasoconstrictor).

For temporary relief of symptoms associated with the common cold, sinusitis or flu including nasal congestion, headache, fever, body aches, and pains.

11. Rx or OTC: OTC

12. RELATED IND/NDA/DMF(s):

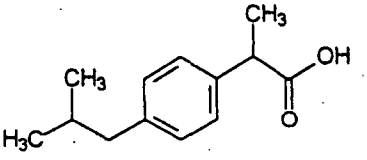
DMF#	TYPE	SUBJECT	HOLDER
		Ibuprofen	
		Pseudoephedrine	
		PVC sheet	
		Blister pack	
		Desiccant	
		Resin	

13. DOSAGE FORM: Tablets

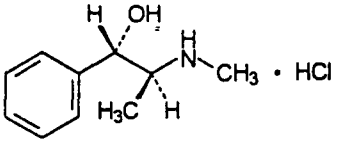
14. POTENCIES: Ibuprofen: 200 mg / Pseudoephedrine HCl: 30 mg

15. CHEMICAL NAME AND STRUCTURE:

Ibuprofen: Benzeneacetic acid, α-methyl-4-(2-methylpropyl),(±)-. $C_{13}H_{18}O_2$. Mol. Wt. 206.29



Pseudoephedrine Hydrochloride: Benzenemethanol, α-[1-(methylamino)ethyl]-, [*S*-(*R**,*R**)]-, hydrochloride. $C_{10}H_{15}NO \cdot HCl$. Mol. Wt. 201.7.



16. RECORDS AND REPORTS: None

17. COMMENTS:

The following sections are not acceptable.

22. Synthesis
23. Raw material control
28. Laboratory controls
29. Stability

18. CONCLUSIONS AND RECOMMENDATIONS:

The application is not approvable (minor).

19. REVIEWER: Gil Kang DATE COMPLETED: 26-MAY-2000

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Chem Review #2

38. Chemistry Comments to be Provided to the Applicant

AADA/ANDA: 75-588 APPLICANT: Pharmaceutical Formulation

DRUG PRODUCT: Ibuprofen/Pseudoephedrine Hydrochloride Tablets USP 200 mg/30 mg

The deficiencies presented below represent MINOR deficiencies

A. Deficiencies:

1. DMF No. for Pseudoephedrine HCl is currently inadequate. The holder has been notified. Please do not respond to this letter until you have obtained a letter from the DMF holder stating that the DMF deficiencies have been addressed.

2. Please provide the result of unidentified impurities for the Ibuprofen certificate of analysis on page 6 of the amendment (December 2, 1999).

3. Please provide the result of other identified and unidentified impurities for the Pseudoephedrine HCl certificate of analysis on page 12-13 in the amendment (December 2, 1999).

4. OGD requests that all production batches continue to be monitored for as an in-process control. If you experience problems in collecting samples, larger samples (no more than 10 dosage units) may be collected. When larger samples are collected, the weight of the sample tested should be equivalent to the dosage used.

5. Please provide the result of the investigation on the with the new sampling thief. Show that the issue is sampling, per se, not the mixing or the sampling technique.

6. Please provide test and specification for ID test "A" of the finished drug product.

7. Please tighten the limits for the total Ibuprofen and Pseudoephedrine HCl impurities of the finished product release and stability based on the actual data. In addition, please provide the names of any other identified Ibuprofen impurities and Pseudoephedrine HCl impurities for the finished product specification.

B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

The firms referenced in the application relative to the manufacturing and testing of the product must be in compliance with cGMPs at the time of approval.

Sincerely yours,

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

CC: ANDA 75-588
ANDA 75-588/ Division File
Field Copy

Endorsements:

HFD-627/G. Kang/
HFD-627/P. Schwartz, Ph.D./5/31/00
HFD-617/E. Hu, PM/6/1/00
V:\FIRMSNZ\PHARMFRM\LTRS&REV\75588NA1.2RD
F/t by: gp/6/2/00
CHEMISTRY REVIEW - Not Approvable - minor

1. CHEMISTRY REVIEW NO.: 3

2. ANDA #: 75-588

3. NAME AND ADDRESS OF APPLICANT:
Pharmaceutical Formulations, Inc.
460 Plainfield Avenue
Edison, New Jersey 08818

4. LEGAL BASIS FOR SUBMISSION:

Reference-Listed Drug: Advil Cold & Sinus

Whitehall Laboratories
Application No. N19771 001

Strength: Ibuprofen (200 mg)
Pseudoephedrine HCl (30 mg)

Paragraph IV certification to the patent No. 4,552,899 (expiring on November 12, 2002 with a pediatric extension to May 12, 2003) is provided in the amendment dated 03-04-99.

Exclusivity: Expired on 9-19-1992

5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME: Ibuprofen Cold & Sinus

7. NONPROPRIETARY NAME:
Ibuprofen/Pseudoephdrine Hydrochloride tablets USP

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

02-19-1999	Date of ANDA submission.
03-04-1999	Revised patent certification and Bio waiver
03-09-1999	Acknowledge letter by Agency
04-19-1999	Paragraph IV patent certification notification
04-26-1999	Bioequivalence telephone amendment
05-21-1999	Minor labeling amendment
05-28-1999	Patent amendment (expiration of 45-day period)
10-12-1999	Deficiency letter based on review #1 (Major)
12-02-1999	Response to deficiency letter
03-17-2000	Labeling amendment
08-28-2000	Deficiency letter based on review #2 (Minor)
10-03-2000	Response to deficiency letter

10. PHARMACOLOGICAL CATEGORY:
Ibuprofen: Anti-inflammatory
Pseudoephedrine Hydrochloride: Adrenergic (vasoconstrictor).

For temporary relief of symptoms associated with the common cold, sinusitis or flu including nasal congestion, headache, fever, body aches, and pains.

11. Rx or OTC: OTC

12. RELATED IND/NDA/DMF(s):

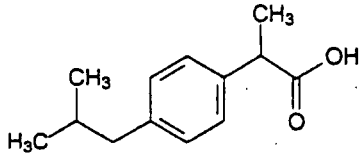
DMF#	TYPE	SUBJECT	HOLDER
		Ibuprofen	
		Pseudoephedrine	
		PVC sheet	
		Blister pack	
		Desiccant	
		Resin	

13. DOSAGE FORM: Tablets

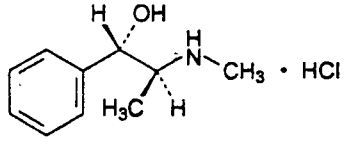
14. POTENCIES: Ibuprofen: 200 mg / Pseudoephedrine HCl: 30 mg

15. CHEMICAL NAME AND STRUCTURE:

Ibuprofen: Benzeneacetic acid, α-methyl-4-(2-methylpropyl),(±)-.
$C_{13}H_{18}O_2$. Mol. Wt. 206.29



Pseudoephedrine Hydrochloride: Benzenemethanol, α-[1-(methylamino)ethyl]-, [*S*-(*R**,*R**)]-, hydrochloride. $C_{10}H_{15}NO \cdot HCl$.
Mol. Wt. 201.7.



16. RECORDS AND REPORTS: None

17. COMMENTS:

The following sections are not acceptable.

22. Synthesis
23. Raw material controls
28. Laboratory controls
29. Stability
32. Labeling

18. CONCLUSIONS AND RECOMMENDATIONS:

The application is not approvable (minor).

19. REVIEWER: Gil Kang DATE COMPLETED: 30-NOV-2000

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Chem Review #3

38. Chemistry Comments to be Provided to the Applicant

ANDA: 75-588 APPLICANT: Pharmaceutical Formulation

DRUG PRODUCT: Ibuprofen/Pseudoephedrine Hydrochloride Tablets USP 200 mg/30 mg

The deficiencies presented below represent MINOR deficiencies

1. DMF No. for Pseudoephedrine HCl is currently inadequate. The holder has been notified. Please do not respond to this letter until you have obtained a letter from the DMF holder stating that the DMF deficiencies have been addressed.

2. Please include the test and specifications for residual solvents in the drug substance controls (Pseudoepedrine and ibuprofen) and provide the results.

3. Your limit for of the finished product release and stability is considerably higher than your actual data suggest. Please tighten the limit based on your release data and room temperature stability data.

Sincerely yours,

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

1. CHEMISTRY REVIEW NO.: 4

2. ANDA #: 75-588

3. NAME AND ADDRESS OF APPLICANT:
Pharmaceutical Formulations, Inc.
460 Plainfield Avenue
Edison, New Jersey 08818

4. LEGAL BASIS FOR SUBMISSION:

Reference-Listed Drug: Advil Cold & Sinus

Whitehall Laboratories
Application No. N19771 001

Strength: Ibuprofen (200 mg)
Pseudoephedrine HCl (30 mg)

Paragraph IV certification to the patent No. 4,552,899 (expiring on November 12, 2002 with a pediatric extension to May 12, 2003) is provided in the amendment dated 03-04-99.

Exclusivity: Expired on 9-19-1992

5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME: Ibuprofen Cold & Sinus

7. NONPROPRIETARY NAME:
Ibuprofen/Pseudoephdrine Hydrochloride tablets USP

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

02-19-1999	Date of ANDA submission.
03-04-1999	Revised patent certification and Bio waiver
03-09-1999	Acknowledge letter by Agency
04-19-1999	Paragraph IV patent certification notification
04-26-1999	Bioequivalence telephone amendment
05-21-1999	Minor labeling amendment
05-28-1999	Patent amendment (expiration of 45-day period)
10-12-1999	Deficiency letter based on review #1 (Major)
12-02-1999	Response to deficiency letter
03-17-2000	Labeling amendment
08-28-2000	Deficiency letter based on review #2 (Minor)
10-03-2000	Response to deficiency letter

10-27-2000	Deficiency letter based on review #3 (Minor)
01-17-2001	Response to deficiency letter (minor amendment)
01-22-2001	Correction of the amendment (01-17-2001)
03-02-2001	Telephone amendment
03-08-2001	Telephone amendment
03-12-2001	Telephone amendment

10. PHARMACOLOGICAL CATEGORY:
Ibuprofen: Anti-inflammatory
Pseudoephedrine Hydrochloride: Adrenergic (vasoconstrictor). For temporary relief of symptoms associated with the common cold, sinusitis or flu including nasal congestion, headache, fever, body aches, and pains.

11. Rx or OTC: OTC

12. RELATED IND/NDA/DMF(s):

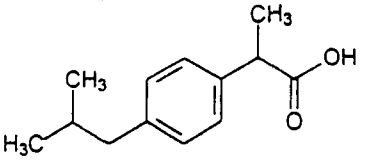
DMF#	TYPE	SUBJECT	HOLDER
		Ibuprofen	
		Pseudoephedrine	
		PVC sheet	
		Blister pack	
		Desiccant	
		Resin	

13. DOSAGE FORM: Tablets

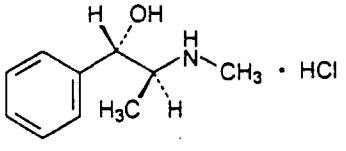
14. POTENCIES: Ibuprofen: 200 mg / Pseudoephedrine HCl: 30 mg

15. CHEMICAL NAME AND STRUCTURE:

Ibuprofen: Benzeneacetic acid, α-methyl-4-(2-methylpropyl),(±)-.
$C_{13}H_{18}O_2$. Mol. Wt. 206.29



Pseudoephedrine Hydrochloride: Benzenemethanol, α-[1-(methylamino)ethyl]-, [*S*-(*R**,*R**)]-, hydrochloride. $C_{10}H_{15}NO \cdot HCl$. Mol. Wt. 201.7.



16. RECORDS AND REPORTS: None

17. COMMENTS:

Telephone amendment 02-MAR-2001 is regarding the revision of the limit of from %.
Telephone amendment 12-MAR-2001 is regarding the impurities for the finished products. The product specifications and stability protocols have been updated to only list degradation impurities since process impurities tested do not increase with time.
BASF's Ibuprofen impurity profiles and Knoll's Pseudoephedrine Hydrochloride impurity profiles are provided.
Both amendments are acceptable.

18. CONCLUSIONS AND RECOMMENDATIONS:

The application is **approvable (tentative)**.

19. REVIEWER: Gil Kang DATE COMPLETED: 13-MAR-2001

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Chem Review #4

1. CHEMISTRY REVIEW NO.: 5

2. ANDA #: 75-588

3. NAME AND ADDRESS OF APPLICANT:
Pharmaceutical Formulations, Inc.
460 Plainfield Avenue
P.O. Box 1904
Edison, New Jersey 08818

4. LEGAL BASIS FOR SUBMISSION:

Reference-Listed Drug: Advil Cold & Sinus

Whitehall Laboratories
Application No. N19771 001

Strength: Ibuprofen (200 mg)
Pseudoephedrine HCl (30 mg)

Paragraph IV certification to the patent No. 4,552,899 (expiring on November 12, 2002 with a pediatric extension to May 12, 2003) is provided in the amendment dated 03-04-99.

Exclusivity: Expired on 9-19-1992

5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME: Ibuprofen Cold & Sinus

7. NONPROPRIETARY NAME:
Ibuprofen/Pseudoephdrine Hydrochloride tablets USP

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

02-19-1999	Date of ANDA submission.
03-04-1999	Revised patent certification and Bio waiver
03-09-1999	Acknowledge letter by Agency
04-19-1999	Paragraph IV patent certification notification
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05-21-1999	Minor labeling amendment
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12-02-1999	Response to deficiency letter
03-17-2000	Labeling amendment
08-28-2000	Deficiency letter based on review #2 (Minor)

10-03-2000	Response to deficiency letter
10-27-2000	Deficiency letter based on review #3 (Minor)
01-17-2001	Response to deficiency letter (minor amendment)
01-22-2001	Correction of the amendment (01-17-2001)
03-02-2001	Telephone amendment
03-08-2001	Telephone amendment
03-12-2001	Telephone amendment
04-17-2001	Tentative approval
11-15-2001	Labeling amendment
01-25-2002	Minor amendment (subject of this review)
03-08-2002	Telephone amendment (Correction)

10. PHARMACOLOGICAL CATEGORY:
Ibuprofen: Anti-inflammatory
Pseudoephedrine Hydrochloride: Adrenergic (vasoconstrictor). For temporary relief of symptoms associated with the common cold, sinusitis or flu including nasal congestion, headache, fever, body aches, and pains.

11. Rx or OTC: OTC

12. RELATED IND/NDA/DMF(s):

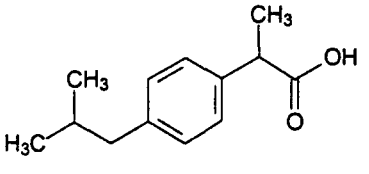
DMF#	TYPE	SUBJECT	HOLDER
		Ibuprofen	
		Pseudoephedrine	
		PVC sheet	
		Blister pack	
		Desiccant	
		Resin	

13. DOSAGE FORM: Tablets

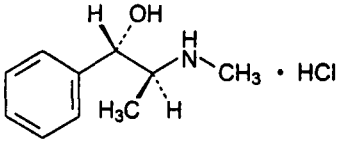
14. POTENCIES: Ibuprofen: 200 mg / Pseudoephedrine HCl: 30 mg

15. CHEMICAL NAME AND STRUCTURE:

Ibuprofen: Benzeneacetic acid, α-methyl-4-(2-methylpropyl),(±)-.
$C_{13}H_{18}O_2$. Mol. Wt. 206.29



Pseudoephedrine Hydrochloride: Benzenemethanol, α-[1-(methylamino)ethyl]-, [*S*-(*R**,*R**)]-, hydrochloride. $C_{10}H_{15}NO \cdot HCl$. Mol. Wt. 201.7.



16. RECORDS AND REPORTS: None

17. COMMENTS:

This amendment (25-JAN-2002) was submitted to update the tentatively approved application for the final approval. Raw material specifications have been revised per USP 25/NF 20. Other than that, no changes have been indicated. Telephone amendment of 08-MAR-2002 was submitted to change the incorrect Ibuprofen specifications that are different from the tentatively approved specifications.

18. CONCLUSIONS AND RECOMMENDATIONS:

The application is **approvable**.

19. REVIEWER: Gil Kang DATE COMPLETED: 11-MAR-2002

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Chem Review #5