

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**40098**

**ADMINISTRATIVE DOCUMENTS**

REVIEW OF PROFESSIONAL LABELING

ANDA

DRAFT - Container Label and Insert Labeling

DATE OF REVIEW: May 25, 1994

ANDA #: 40-098

NAME OF FIRM: Mova Pharmaceutical Corporation

NAME OF DRUG: Generic: Acetaminophen and Codeine Phosphate  
Oral Solution, USP 120 mg/12 mg per  
5 mL

DATE OF SUBMISSION: February 25, 1994

COMMENTS:

CONTAINER:

1. FRONT PANEL - The statement "\*Warning-May be habit forming" should be relocated to immediately below "Codeine Phosphate...12 mg" and also should have an asterisk.
2. RIGHT SIDE PANEL - Please include the temperature range. (i.e., 15°-30°C [59°-86°F])
3. Include an asterisk after "CODEINE PHOSPHATE" in the established name.
4. We see no need for the statement "Orange Colored". You may delete *if you wish. (ymille 3/4/94)*

INSERT:

Revise your insert labeling to be in accord with the Labeling Guidance for Acetaminophen with Codeine Phosphate Oral Solution, USP (revised December 1993).

RECOMMENDATIONS:

1. Inform the firm of the above comments.
2. Request the firm revise their container labels and insert labeling, then prepare and submit *draft* printed container labels and *final* insert labeling.
3. Please include Labeling Guidance with letter out.

4. FOR THE RECORD

a. Storage/dispensing recommendations:

ANDA: controlled room temperature, do not refrigerate; tight, light resistant container.

NDA: room temperature, do not refrigerate; tight, light-resistant container.

USP: tight, light-resistant container.

b. The alcohol content (v/v of absolute alcohol) of the firm's product has been calculated as 7.0% v/v absolute alcohol using information from the following sources:

i. A manufacturing order for liquids listing a batch size of            Liters containing a            Kg mass of Alcohol, USP (page 353).

ii. The specific gravity of alcohol as            g/mL (Kg/L).

iii. The average proportion of Alcohol USP as

c. This ANDA is packaging this light-sensitive product in an HDPE white bottle.

5. NOTE TO THE CHEMIST

→ Please verify the above calculations, for alcohol.

Adolph Vezza

cc: ANDA 40-098

HFD-613/AVezza/JPhillips (no cc)  
mpd/6/16/94; 40098MAR.94

Review  
Final

/S/ 6/16/94  
/S/ 6/20/94

REVIEW OF PROFESSIONAL LABELING #2

Original Amendment (MAJOR)

DRAFT - Insert Labeling and FPL - Container Labels

DATE OF REVIEW: January 23, 1995

ANDA #: 40-098

NAME OF FIRM: Mova Pharmaceutical Corporation

NAME OF DRUG: Acetaminophen and Codeine Phosphate Oral Solution,  
USP 120 mg/12 mg per 5 mL

DATE OF SUBMISSION: December 5, 1994

COMMENTS:

CONTAINER: 473 mL

Front Panel - Please place the following statement  
underneath the "WARNING - May be habit forming" statement:

Alcohol ...7%

INSERT:

1. DESCRIPTION

- a. Third paragraph, line 1  
... -ol phosphate...
- b. "Each 5 mL contains" statement - Delete
- c. Please include the description of the flavor.

2. PRECAUTIONS

- a. Nursing Mothers, line 4 - Delete the extra space  
between the words "nursing" and "or".
- b. Pediatric Use - ... in pediatric patients below  
the age...

3. DOSAGE AND ADMINISTRATION

- a. Paragraph 1, line 5 -...appreciable...  
["appreciable" rather than

- b. Children (7 to 12 years) - To be consistent with the other dosage statements, indent the "10 mL" so it is in alignment with the "5 mL" from the line below.

4. HOW SUPPLIED

We encourage the inclusion of your storage conditions as seen on the label and the "CAUTION": Federal law..." statement.

RECOMMENDATIONS:

1. Inform the firm of the above comments.
2. Request the firm revise their container labels and insert labeling, then prepare and submit final printed container labels and insert labeling.
3. FOR THE RECORD
  - a. Storage/dispensing recommendations:
    - ANDA: controlled room temperature, do not refrigerate; tight, light resistant container.
    - NDA: room temperature, do not refrigerate; tight, light-resistant container.
    - USP: tight, light-resistant container.
  - b. This ANDA is packaging this light-sensitive product in an HDPE white bottle.

Adolph Vezza

cc: ANDA 40-098  
HFD-613/AVezza/CZimmermann/JPhillips (no cc).  
mpd/2/15/95; (95) 40098DEC.94  
Review  
final

2/15/95  
2/15/95  
7S/ 2/16/95

RECORD OF TELEPHONE CONVERSATION/MEETING

DATE

11/4/91

NDA NUMBER

40-098

IND NUMBER

TELECON/MEETING

INITIATED BY

APPLICANT/  
SPONSOR  
 FDA

MADE

BY TELE-  
PHONE  
 IN PERSON

PRODUCT NAME

APAP / Codeine P<sub>o</sub>  
Oral Solution  
USP

FIRM NAME

MOVA

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD

Dale Kaufman

TELEPHONE NO.

809-746-8500

Called firm and related comments to their fax of 10/7/94 providing clarification to our NA ltr dated 8/10/94. (see attached fax)

Item 2a) - Spectra not clearly marked or labeled, - is found on Pg 153-4 and it is unclear which is the USP Reference Std Spectra clearly mark & indicate the spectra & explain calibration.

3a) We need complete quantitative composition statement. DWT authorization is required.

4a) This is routine request. NDS source can even be hand written in an Batch Record & Formula cards.

4d) Translation is inadequate. Footnotes other notations and comments are not clearly translated must provide certified translation perhaps on the same sheet to clarify what's being translated & where.

4c) An explanation is adequate for this response.

7d) Need values not ✓ marks & translation does not provide this.

8a) The explanation is an adequate response.

9a) Assay must be stability indicating and demonstrate quantitatively its ability to pick up signal impurities.

SIGNATURE

D Kaufman felt these clarifications  
Dwelling W. ASD, OGD

DIVISION

were helpful & thanked us.

RECORD OF TELEPHONE CONVERSATION/MEETING

DATE

5/26/95

NDA NUMBER

40-098

IND NUMBER

TELECOM/MEETING

INITIATED BY

APPLICANT/  
SPONSOR  
 FDA

MADE

BY TELEPHONE  
 IN PERSON

PRODUCT NAME

Acetaminophen &  
Codeine P<sub>4</sub> USP Oral  
Solution, 120mg/12mg/5ml

FIRM NAME

Nova Pharmaceutical  
Corp.

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD

Dale Robson  
Carmen Delia Carter

TELEPHONE NO.

809-746-8500

Firm called back for clarification request fax of 5/15/95.

• Item A.1.

We need acceptable limits set for OVI's even though NDS manufacturers certify drug substance is free from and are not used in its manufacture. Firm should use USP as reference as well as NDS manufacturers' COA for setting these limits.

• Item 4.b. We need line by line

certified translation of executed batch record. A page by page english representation of the executed batch record.

• Item 6.a We do want a list of

all excipients used included in the stability report. The formulation and/or composition of drug product must be included in the stability data report.

• Also, we need a set of limits for degradation products/related substances/impurities for Acetaminophen & Codeine P<sub>4</sub>. These can be determined from drug substance COAs.

SIGNATURE

/S/

DIVISION

OGD/chem II/Br 7.





Professional Package Insert Labeling: Satisfactory as of  
4-22-96 submission.

Revisions needed post-approval:

The firm must add the following statement immediately  
after the listing of the inactive ingredients in the  
DESCRIPTION section of the insert labeling:  
Sodium hydroxide may be added to adjust the pH.

**BASIS OF APPROVAL:**

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Tylenol with Codeine  
Elixir

ANDA Number: 85-057

ANDA Drug Name: Tylenol with Codeine Oral Solution

ANDA Firm: McNeilab. Inc. (R.W. Johnson)

Date of Approval of ANDA Insert and supplement #:

Has this been verified by the MIS system for the ANDA?  
Yes No

Was this approval based upon an OGD labeling guidance?  
Yes

If yes, give date of labeling guidance: 12/93 ✓

Basis of Approval for the Container Labels: LABELING GUIDANCE

Basis of Approval for the Carton Labeling: N/A

Other Comments: The established name for this drug  
product has been changed in the USP from  
an "elixir" to an "oral solution".

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## REVIEW OF PROFESSIONAL LABELING CHECK LIST

Applicant's Established Name	Yes	No	N.A.
Different name than on acceptance to file letter? See above approval summary	X		
Is this product a USP item? If so, USP supplement in which verification was assured.	X		
Is this name different than that used in the Orange Book?		X	

If not USP, has the product name been proposed in the PF?			X
<b>Error Prevention Analysis</b>			
<i>PROPRIETARY NAME</i>			
Has the firm proposed a proprietary name? If yes, complete this subsection.		X	
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?			x
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified?			x
<i>PACKAGING</i> -See applicant's packaging configuration in FTR			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.		X	
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.		X	
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?			X
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?		X	
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?		X	
Are there any other safety concerns?		X	
<i>LABELING</i>			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?			X
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	
<b>Error Prevention Analysis: LABELING (Continued)</b>	<b>Yes</b>	<b>No</b>	<b>N.A.</b>
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)		X	
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?			X

Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.			X
<b>Scoring:</b> Describe scoring configuration of RLD and applicant (page #) in the FTR			X
Is the scoring configuration different than the RLD?			X
Has the firm failed to describe the scoring in the HOW SUPPLIED section?			X
<b>Inactive Ingredients:</b> (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?	x		
Do any of the inactives differ in concentration for this route of administration?		x	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		x	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement?	x		
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		x	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?		x	
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			x
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)		x	
<b>USP Issues:</b> (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?		x	
Does USP have labeling recommendations? If any, does ANDA meet them?		x	
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?	x		
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling.		x	
<b>Bioequivalence Issues:</b> (Compare bioequivalency values: insert to study. List Cmax, Tmax, T 1/2 and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?		x	
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		x	
<b>Patent/Exclusivity Issues:</b> FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.			

FOR THE RECORD:

1. This review was based on the Labeling Guidance for Acetaminophen and Codeine Phosphate Oral Solution USP (rev. 12/93).
2. The container size for both the RLD and this ANDA is a pint.
3. The drug is light-sensitive. The RLD markets their containers in amber glass while the ANDA will be marketed in HDPE white containers (light-resistant).
4. This ANDA was granted a bio waiver 6-29-94.
5. Storage/dispensing recommendations:

USP:           tight, light-resistant

RLD:           room temperature, do not refrigerate; tight, light-resistant container

ANDA:          CRT (15-30°C), do not refrigerate; tight, light-resistant container

6. As previously mentioned, the firm has failed to list in their listing of inactive ingredients in the DESCRIPTION section (see page 1 of Attachment II of the 12-5-94 submission). We will request that the firm correct this at first opportunity post-approval.

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Primary Reviewer

4/26/96  
Date

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Acting Team Leader,  
Labeling Rev. Branch

4/26/96  
Date

cc:  
ANDA 40-098  
Dup/Division File  
HFD-613/AVezza/JGrace  
HFD-600

Review

# REVIEW OF PROFESSIONAL LABELING

## DIVISION OF LABELING AND PROGRAM SUPPORT

### LABELING REVIEW BRANCH

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Date of Review: 2-6-96                      Date of Submission: 7-7-95

Primary Reviewer: Adolph Vezza

Secondary Reviewer:

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ANDA Number: 40-098

Review Cycle: Third

Applicant's Name [as seen on 356(h)]: Mova Pharmaceutical Corp.

Manufacturer's Name (If different than applicant): SAME (see page  
318 - Vol 1.1)

Proprietary Name: N/A

Established Name: Acetaminophen and Codeine Phosphate Oral  
Solution USP, 120 mg/12 mg per 5 mL

LABELING DEFICIENCIES, WHICH ARE TO BE INCORPORATED WITH THE  
CHEMISTRY COMMENTS TO THE FIRM:

[NOTE: These deficiencies can be located on the x-drive as  
detailed in notes from Ted Sherwood regarding the New X-Drive]

A. CHEMISTRY DEFICIENCIES

B. LABELING DEFICIENCIES

INSERT

DESCRIPTION - Revise the molecular weight of  
acetaminophen to read 151.17 as per USP 23.

Please revise your labeling, as instructed above, and submit final print insert labeling. Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

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Established Name: Acetaminophen and Codeine Phosphate Oral  
Solution USP 120 mg/12 mg per 5 mL

Is this the same name, as seen on the Acceptance to File, letter? NO. The letter refers to this product as an elixir. This has been changed in the USP. It is now known as "oral solution".

Is this product a USP item? Yes

List the USP supplement in which verification was assured:  
USP 23

What is the name used in the Orange Book? Acetaminophen and Codeine Phosphate Oral Solution

Has the product name been proposed in the PF? N/A

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ERROR PREVENTION ANALYSIS

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A. PROPRIETARY NAME

1. Has the firm proposed a proprietary name? No

If yes, continue on to question 2, otherwise go to section B.

2. Do you find the name objectionable? Yes No

If yes, list your reasons:

a. Misleading: Yes No

If yes, list reasons and incorporate into

your comments to the firm:

b. Sounds or looks alike to another name:  
Yes No  
If Yes, list:

c. USAN Stem present: Yes No

d. Prefix's or Suffixes present: Yes No

3. Has the name been forwarded to the Labeling and Nomenclature Committee? Yes No

a. If Yes, what were the recommendations of the committee?

\_\_\_\_\_ Accept \_\_\_\_\_ Unaccept \_\_\_\_\_ Concern Raised

\_\_\_\_\_ Comment

b. If the name has been found unacceptable, give the date these recommendations were forwarded to the firm?

**B. PACKAGING:**

1. List the packaging configuration(s) of the RLD (reference listed drug) and the ANDA: Both are packaged in pint bottles.

2. Is the ANDA applicant proposing a new packaging configuration which has never been approved by in ANDA or NDA? No

If yes, describe:

3. Could the package be considered a reasonable package to be dispensed to the patient? For example, a "BID" administered drug in a package size of 60 or 120 might be considered unit-of-use. NO

If yes, the Poison Prevention Packaging Act (PPPA) may require a CRC cap. Does the package(s) comply with the PPPA? N/A

4. Does the package proposed have any safety and/or regulatory concerns? For example:

a. If this product is an intravenous product packaged in a syringe, what is the patient outcome if given by direct intravenous injection? N/A

b. Do the DOSAGE AND ADMINISTRATION and INDICATIONS sections of the labeling support the packaging

configuration? YES. The bottle is meant to be used as a stock bottle and not to be dispensed in its entirety to a patient.

i. Is the strength and/or concentration of the product supported by the insert labeling?  
YES

c. Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap correct? Container is HDPE white - Innovator has amber glass - per L. Tang ANDA container is light-resistant

d. Are individual cartons required? No  
Factors to consider are:  
1) Does the innovator have individual cartons?  
No  
2) Is the product sensitive to light and is it unlikely that the product will be retained inside a multiple unit carton until the time of use or until the contents have been used? Dispensing recommendations call for light-resistant container. Container is light-resistant per chemist.  
3) Is there a need for the package insert to accompany the product? YES

e. Any other concerns? NO

C. LABELING:

1. Is the name of the drug clearly printed and is it the most prominent information on the label? YES
2. Is the strength clearly expressed? YES
3. Are multiple strengths of the same product clearly differentiated? n/a
4. Is the corporate logo larger than one-third the size of the container label? [NOTE: not a requirement, but seen in the ASHP Guidelines]. NO
5. Does the color of the label relay any special significance to the professional (i.e. Synthroid and Premarin have a matching container color with the color of the tablet)? No
6. Does the RLD make special differentiation for this label (i.e., Pediatric strengths vs Adult or Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA, would be required for the ANDA)? No

7. Is the Manufactured By/Distributor statement correct and consistent between labels and labeling? YES
8. If a unit-dose carton, does it contain the child-resistant statement? N/A
9. Is the most recently approved innovator labeling being used as a model? To determine this, use the MIS to determine the most recent labeling supplement approval date for the NDA. This MIS data is to be printed and attached to the first review and the final review as confirmation that the correct model is being used.  
N/A. Labeling Guidance is used as model.
10. For solid oral dosage forms, have identifying markings (imprints, embossing, debossing) been described in the HOW SUPPLIED section? N/A
11. Has the firm adequately supported any compatibility or stability claims which appear in the insert labeling? Include information describing where the chemist has confirmed the data has been adequately supported. N/A

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**SCORING:**

N/A. This ANDA is an oral solution.

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**INACTIVE INGREDIENTS:**

On what page of the application are the inactive ingredients listed: page 49 V 1.1

Does the product contain alcohol? YES. If so, has the accuracy of the statement been confirmed? YES. See labeling review dated 5-25-94

Have all of the inactives previously been used in this concentration for this route of administration? YES.

Any adverse effects anticipated from the inactive ingredients (i.e. benzyl alcohol in neonates)? NO. The product does contain 7% alcohol which is stated on the main panel of the container label.

Are all the inactives cited in the composition statement listed in the DESCRIPTION section? Yes - *Not a part*  
*no.*

If no, list the inactives not present in the insert:

Has the term "any other ingredients" been used to protect a trade secret? NO. If so, has the firm adequately supported the claim of a trade secret? N/A

If the composition statement lists Opaspray # or Opacode #, are the coloring agents listed in the Description section? N/A

At a minimum, gelatin, the coloring agents and antimicrobial preservatives found in capsule shells must be listed in the Description section. Does the insert comply? N/A

Inks: Only dyes used in the imprinting inks must be listed. Coloring agents such as the iron oxides do not need to be listed. Has this been confirmed? N/A

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**USP ISSUES:**

List the USP/NDA/ and ANDA dispensing recommendations:

USP:           tight, light-resistant container  
RLD:           tight, light-resistant container  
ANDA:          tight, light-resistant container

Do the container recommendations meet or exceed these recommendations?   YES

Does the USP have any labeling recommendations?   As above.

If any, does the ANDA meet the requirements?   Yes

Is the product light sensitive? Dispensing recommendation is tight, light-resistant container.

If yes, is the NDA in a light-resistant container? NDA is in a light-resistant container.

If yes, is the ANDA in a light-resistant container? YES

Does the USP Description and Solubility information agree with the information appearing in the insert labeling? If not, the USP information should be used. However, since the USP often lists numerous solvents, please include only those which appear in the innovator labeling. N/A. There is no solubility information mentioned in the insert labeling.

Storage recommendations of the USP/NDA/ANDA:

USP:           NONE  
RLD:           room temperature, do not refrigerate  
ANDA:          CRT (15<sup>0</sup>-30<sup>0</sup>C), do not refrigerate

If the storage recommendations differ from the USP or the innovator, have they been adequately supported and is the difference acceptable? N/A

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**BIOEQUIVALENCY ISSUES:**

Does the insert labeling have any reference to a food effect or a no-effect? NO

If yes, was a food study performed?

Has the CLINICAL PHARMACOLOGY section of the insert labeling, as seen in the NDA, been modified for this ANDA? NO. There is no NDA for this product. Review is based on Labeling Guidance for Acetaminophen and Codeine Phosphate Oral Solution (REV. 12/93).

List the bioequivalency values, for appropriate dosage forms, found in the insert labeling and list the values as seen in the approved bio study (i.e., Cmax, Tmax, T1/2, AUC): Only pharmacokinetic parameter in insert is T1/2 of codeine. Active and inactive ingredients identical to RLD. This ANDA was thus granted a bio waiver.

Date Bioequivalency Study found Acceptable: Bio waiver granted 6-29-94.

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APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval):

Do you have 12 Final Printed Labels and Labeling? No  
If no, list why:

Container Labels: Satisfactory in FPL as of 7-7-95  
submission.

Carton Labeling: N/A

Unit Dose Blister Label: N/A

Unit Dose Carton Label: N/A

Professional Package Insert Labeling: Draft labeling  
submitted

Patient Package Insert Labeling: N/A

Auxiliary Labeling: N/A

Revisions needed post-approval:

**BASIS OF APPROVAL:**

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Tylenol with Codeine  
Elixir

NDA Number: ANDA

NDA Drug Name: (ANDA) Tylenol with Codeine Oral Solution

NDA Firm: R. W. Johnson (ANDA)

Date of Approval of NDA Insert and supplement #:

Has this been verified by the MIS system for the NDA?  
Yes No

Was this approval based upon an OGD labeling guidance?  
Yes

If yes, give date of labeling guidance: 12/93

Basis of Approval for the Container Labels: LABELING GUIDA  
NCE

Basis of Approval for the Carton Labeling: N/A

Other Comments: Firm notified of need for insert labeling in FPL (12) and of minor change requested (MW of Codeine). Firm to submit FPL in approx. 2 weeks. (ASAP) Firm is in Puerto Rico. See TELECON dated 2-6-96. Chemistry is satisfactory per L. Tang (2-6-96).

**PATENT/EXCLUSIVITY ISSUES:**

List the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity: N/A

Expiration date and listing of all patents, exclusivities etc.: N/A

**NOTES/QUESTIONS TO THE CHEMIST:**

Chemist has verified that container is light-resistant.

**FOR THE RECORD:**

Firm was notified on 2-6-96 by A. Vezza to submit FPL insert labeling (12) to the ANDA as a telephone amendment. Minor revision (MW of codeine) to be made at this time.

          /S/            
Primary Reviewer

                  2/7/96                    
Date

          /S/            
Team Leader, Labeling Rev. Branch

                  2-7-96                    
Date

cc:  
ANDA 40-098  
Dup/Division File