SciRegs
Scientific and Regulatory Affairs Consulting

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Dockets Managements Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
1240 Parklawn Dr.
Rockville, MD 20857

**Reference: Citizens Petition- Suitability Petition for Hydrocodone Bitartrate / Ibuprofen 5/ 200 mg Tablets**

Dear Sir/Madam,

Pursuant to *Code of Federal Regulations* Title 21 §314.93 SciRegs Consulting hereby submits a Suitability Petition on behalf of Interpharm Inc., to request a change from a listed drug. Reference is also made to Code *of Federal Regulations* Title §10.20, §10.30, §25.21, §25.31(a), §314.92, §314.93 and §314.55 (c).

Interpharm Inc. intends to submit an Abbreviated New Drug Application for a combination product, which is the same as the listed drug, and a second strength that differs from the listed drug in the strength of one of the active ingredients. The Reference Listed Drug is Hydrocodone Bitartrate/ Ibuprofen 7.5 /200 mg Tablet. Interpharm Inc. intends to market an Hydrocodone Bitartrate/ Ibuprofen 5 / 200 mg Tablet that would provide a lower dose of Hydrocodone bitartrate.

A second product Acetaminophen/Hydrocodone bitartrate is also marketed where the active ingredients are the same pharmacological and therapeutic class, and the dose of hydrocodone bitartrate is 5 mg. The hydrocodone bitartrate can therefore be expected to have the same therapeutic effect.

For the purpose of this submission a comparison of the proposed formulations for both ANDA strengths is provided along with a comparison of the label for the reference listed drug and the proposed lower strength.

This concludes our petition. Please feel free to contact me at 410-309-3145 and FAX at 410-309-6145 should have any questions.

Sincerely yours,

C. Jeanne Taborsky

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02P-0270

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## A. Action Requested §10.30 (a)

The petitioner is seeking permission to file an abbreviated new drug application (ANDA) for a product that is changed from a listed drug in the strength of one of the active ingredients in a combination product. The petitioner requests that the Commissioner amend the regulation *Code of Federal Regulations* Title 21 § 314.92 to allow the applicant to file an Abbreviated New Drug Application (ANDA) to the FDA, Office of Generic Drugs consideration of approval for market of a lower strength of the Reference Listed Drug.

## B. Statement of grounds §10.30 (b)

Pursuant to *Code of Federal Regulations* Title 21 § 314.93 (a), (b), (c) the petitioner is requesting to file a ANDA for a drug wherein there is a change from the listed drug for which the agency will accept a petition; (b) to allow the applicant to file an Abbreviated New Drug Application to the FDA, Office of Generic Drugs consideration of approval for market of a lower strength of the Reference Listed Drug.

### 1. *Code of Federal Regulations* Title 21 § 314.93 (d) Identification of Reference Listed Drug

The Reference Listed Drug is Vicoprofen® (hydrocodone bitartrate /ibuprofen) 7.5 mg/ 200 mg manufactured by the NDA holder Abbott Laboratories as a C-III; an immediate release oral combination opioid/analgesic used for a range of pain indications.

| Appl No | TE Code | RLD | Active Ingredient | Dosage Form; Route | Strength | Proprietary Name | Applicant |
|---|---|---|---|---|---|---|---|
| 020716 | | Yes | HYDROCODONE BITARTRATE; IBUPROFEN | Tablet; Oral | 7.5MG; 200MG | VICOPROFEN® | ABBOTT |

A similar second combination product, Hydrocodone Bitartrate 5 mg marketed with Acetaminophen where the requested strength of hydrocodone bitartrate is present as follows:

| Appl No | TE Code | RLD | Active Ingredient | Dosage Form; Route | Strength | Proprietary Name | Applicant |
|---|---|---|---|---|---|---|---|
| 087677 | AA | No | ACETAMINOPHEN; HYDROCODONE BITARTRATE | Tablet; Oral | 500MG; 5MG | HY-PHEN | ASCHER |
| 040309 | AA | No | ACETAMINOPHEN; HYDROCODONE BITARTRATE | Tablet; Oral | 500MG; 10MG | HYDROCODONE BITARTRATE AND ACETAMINOPHEN | BARR |
| 040307 | AA | No | ACETAMINOPHEN; HYDROCODONE BITARTRATE | Tablet; Oral | 500MG; 2.5MG | HYDROCODONE BITARTRATE AND ACETAMINOPHEN | BARR |
| 040308 | AA | No | ACETAMINOPHEN; HYDROCODONE BITARTRATE | Tablet; Oral | 500MG; 5MG | HYDROCODONE BITARTRATE AND ACETAMINOPHEN | BARR |

**2. *Code of Federal Regulations* Title 21 § 314.93 (d) Comparison of similarly dose proportional formulations for the Reference Listed Drug and the subject of this petition**

| Composition (mg per tablet) | | | |
|---|---|---|---|
| Ingredient | 7.5 / 200 mg | 5 / 200 mg | Purpose in formulation |
| Hydrocodone Bitartrate, USP | 7.5 | 5 | Active Ingredient |
| Ibuprofen, USP | 200 | 200 | Active Ingredient |
| Colloidal Silicon Dioxide, NF | 8.0 | 8.0 | Glidant |
| Pregelatinized Starch, NF | 109.0 | 109.0 | Binder/disintegrant/diluent |
| Microcrystalline Cellulose, NF | 42.5 | 45.0 | Binder |
| Croscarmellose Sodium, NF | 30.0 | 30.0 | Binder |
| Magnesium Stearate, NF | 3.0 | 3.0 | Glidant/lubricant |
| Opadry II White 49B18272 | 4 | 4 | Coating |
| Opadry Clear YS-1-7006 | 1 | 1 | Coating |
| Total | 405.0 | 405.0 | |

| | Ingredient |
|---|---|
| Opadry II White 49B18272 | Polydextrose |
| | Titanium dioxide |
| | Hydroxypropyl methyl cellulose |
| | Macrogol/polyethylene glycol 200 |
| | Carnauba wax |
| Opadry Clear YS-1-7006 | Hydroxypropyl methyl cellulose |
| | Macrogol/polyethylene glycol 200 |

**3. *Code of Federal Regulations* Title 21 § 314.93 (d) Labeling of Reference Listed Drug and Proposed Product HYDROCODONE BITARTRATE/ IBUPROFEN 5/200 mg**

Attachments

Sample label of RLD
Draft sample label of same strength proposed generic drug
Draft sample label of lower strength proposed generic drug
Side by side comparison of label

Sample insert for RLD
Draft sample insert of generic drug
Side-by-side comparison

**4. Request for Waiver for Pediatric Studies**

A waiver from having to conduct pediatric studies on the lower strength of the drug, the subject of this petition is not required (as per conversation with Gregory Davis, Branch Chief, Regulatory Support Branch, HFD-615 (p301-827-5862)(f301-594-1174)

**C. Environmental impact §10.30 (c)**

The petitioner claims a categorical exclusion under this chapter *Code of Federal Regulations* Title 21 § 25.31(a). This petition applies to a drug, which will not be administered at a higher dosage level, for a longer duration or for different indications than were previously in effect. To the best of the petitioner's knowledge, no extraordinary circumstances, as outlined in *Code of Federal Regulations* Title 21 § 25.21 exist.

**D. Economic impact §10.30 (d)**
**(Not yet requested)**

**E. Certification §10.30 (e)**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

C. Jeanne Taborsky

June 12, 2002

Date

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