

the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless an exemption is granted because there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose the disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury with the probable benefit to health from using the device outweighing the risk of injury or illness from its use. This takes into account the probable risks and

benefits of currently available devices or alternative forms of treatment.

The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD

provisions under section 520(m) of the FD&C Act.

The number of respondents in tables 1 and 2 of this document are an average from data for the previous 3 years, *i.e.*, fiscal years 2008 to 2010. The number of annual reports submitted under section 814.126(b)(1) in table 1 reflects 43 respondents with approved HUD applications. Likewise, under section 814.126(b)(2) in table 2, the number of recordkeepers is 43.

In the **Federal Register** of September 7, 2011 (76 FR 55394), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
814.102	17	1	17	40	680
814.104	5	1	5	320	1,600
814.106	5	5	25	50	1,250
814.108	47	1	47	80	3,760
814.116(e)(3)	3	1	3	1	3
814.124(a)	22	1	22	1	22
814.124(b)	12	1	12	2	24
814.126(b)(1)	43	1	43	120	5,160
Total					12,499

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR Section	Number of recordkeeper	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
814.126(b)(2)	43	1	43	2	86

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 27, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 [Docket No. FDA-2008-P-0555]

Determination That HYCODAN (Hydrocodone Bitartrate and Homatropine Methylbromide) Tablets, 5 Milligrams/1.5 Milligrams, and HYCODAN (Hydrocodone Bitartrate and Homatropine Methylbromide) Oral Solution, 5 Milligrams/5 Milliliters and 1.5 Milligrams/5 Milliliters, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that HYCODAN (hydrocodone bitartrate and homatropine methylbromide) tablets, 5 milligrams (mg)/1.5 mg, and HYCODAN (hydrocodone bitartrate and homatropine methylbromide) oral solution, 5 mg/5 milliliters (mL) and 1.5 mg/5 mL, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for hydrocodone bitartrate and homatropine methylbromide tablets, 5 mg/1.5 mg, and HYCODAN (hydrocodone bitartrate and homatropine methylbromide) oral solution, 5 mg/5 mL and 1.5 mg/5 mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

HYCODAN (hydrocodone bitartrate and homatropine methylbromide) tablets, 5 mg/1.5 mg, and HYCODAN (hydrocodone bitartrate and homatropine methylbromide) oral solution, 5 mg/5 mL and 1.5 mg/5 mL, are the subject of NDA 05-213, held by Endo Pharmaceuticals, and initially approved on March 23, 1943. In 1982, a Drug Efficacy Study Implementation

review concluded that HYCODAN syrup, tablets, and powder were effective "for the symptomatic relief of cough." (47 FR 23809, June 1, 1982). Subsequently, the sponsor submitted an NDA for HYCODAN (hydrocodone bitartrate and homatropine methylbromide) tablets, 5 mg/1.5 mg, and HYCODAN (hydrocodone bitartrate and homatropine methylbromide) oral solution, 5 mg/5 mL and 1.5 mg/5 mL, which was approved on July 26, 1988. HYCODAN is indicated for the symptomatic relief of cough in adults and children 6 years of age and older.

In a letter dated January 4, 2008, Endo Pharmaceuticals notified FDA that HYCODAN (hydrocodone bitartrate and homatropine methylbromide) tablets, 5 mg/1.5 mg, were being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. Vintage Pharmaceutical, Inc., submitted a citizen petition dated October 15, 2008 (Docket No. FDA-2008-P-0555), under 21 CFR 10.30, requesting that the Agency determine whether HYCODAN (hydrocodone bitartrate and homatropine methylbromide) tablets, 5 mg/1.5 mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not request it, FDA has determined, on its own initiative, whether the oral solution dosage form was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that HYCODAN (hydrocodone bitartrate and homatropine methylbromide) tablets, 5 mg/1.5 mg, and HYCODAN (hydrocodone bitartrate and homatropine methylbromide) oral solution, 5 mg/5 mL and 1.5 mg/5 mL, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that HYCODAN (hydrocodone bitartrate and homatropine methylbromide) tablets, 5 mg/1.5 mg, or HYCODAN (hydrocodone bitartrate and homatropine methylbromide) oral solution, 5 mg/5 mL and 1.5 mg/5 mL, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of HYCODAN (hydrocodone bitartrate and homatropine methylbromide) tablets, 5 mg/1.5 mg, and HYCODAN (hydrocodone bitartrate and homatropine methylbromide) oral solution, 5 mg/5 mL and 1.5 mg/5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse

events. We have found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list HYCODAN (hydrocodone bitartrate and homatropine methylbromide) tablets, 5 mg/1.5 mg, and HYCODAN (hydrocodone bitartrate and homatropine methylbromide) oral solution, 5 mg/5 mL and 1.5 mg/5 mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to HYCODAN (hydrocodone bitartrate and homatropine methylbromide) tablets, 5 mg/1.5 mg, or HYCODAN (hydrocodone bitartrate and homatropine methylbromide) oral solution, 5 mg/5 mL and 1.5 mg/5 mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0868]

Draft Guidance for Industry on Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices." This draft guidance responds to stakeholder requests for specific guidance on FDA's current views on how manufacturers and distributors (firms) of prescription human and animal drug products and