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December 26, 2013

VIA FEDERAL EXPRESS

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Citizen Petition - Opposition to Upscheduling of Certain Hydrocodone Combination Products from Schedule III to Schedule II

Dear Sir or Madam:

The undersigned, on behalf of an unnamed client, submits this petition under 21 U.S.C. § 505 of the Federal Food, Drug, and Cosmetic Act ("FDCA") and 21 U.S.C. § 811 *et seq.* of the Controlled Substances Act ("CSA"), and their implementing regulations including but not limited to 21 C.F.R. § 10.30, 21 C.F.R. Part 300 *et seq.* and 21 C.F.R. Part 1300 *et seq.*, to request that, should the Commissioner of Food and Drugs formally submit recommendations to the U.S. Department of Health and Human Services ("HHS") to reclassify hydrocodone combination products as Schedule II drugs (as defined by the CSA), that such rescheduling be limited only to hydrocodone combination products that contain hydrocodone bitartrate in a strength of 5 mg or higher in dosage. All hydrocodone combination products that contain less than 5 mg of hydrocodone active ingredient should remain in Schedule III.

Introduction

In 2009, the U.S. Drug Enforcement Administration ("DEA") asked HHS for a recommendation regarding whether to change the schedule for hydrocodone combination products, such as Vicodin® (hydrocodone bitartrate and acetaminophen) oral tablets. The proposed change involved the drugs' rescheduling from Schedule III to Schedule II of the CSA, which, if adopted, would increase significantly the controls required for these products – thereby restricting their access to the patients who need them.

Although the FDA publicly disagreed with this reclassification for many years, it appears that the FDA has now changed course. Specifically, on October 24, 2013, Dr. Janet Woodcock, Director of the U.S. Food and Drug Administration's ("FDA" or "the Agency") Center for Drug

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Evaluation and Research ("CDER"), issued a statement revealing the Agency's plan to submit a formal recommendation package to HHS to reclassify hydrocodone combination products from Schedule III into Schedule II. *See* FDA/CDER, Statement on Proposed Hydrocodone Reclassification from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Oct. 24, 2013, *available at* http://www.fda.gov/drugs/drugsafety/ucm372089.htm. According to Dr. Woodcock, the Agency's submission of such recommendation will begin a process that will lead to a final decision by DEA on the "upscheduling" of these products.

A. Action Requested

For the myriad of public policy reasons set forth below, the undersigned requests that the Commissioner of Food and Drugs refrain from submitting the stated recommendation to HHS to reclassify hydrocodone combination products that contain hydrocodone bitartrate in a strength that is lower than 5 mg in strength into Schedule II.

We believe that, while it may be appropriate to upschedule the higher-strength hydrocodone combination products to Schedule II (namely, those containing 5 mg, 7.5 mg, and 10 mg of hydrocodone bitartate), we do not believe that it is appropriate, warranted, or a good public policy decision to upschedule hydrocodone combination products lower than 5 mg in strength into Schedule II (e.g., 2.5 mg, up to but not including 5 mg). This request strikes an important balance between adding Schedule II controls to high-strength versions of the drug while allowing patients to keep a low-strength version of this safe and effective pain medication.

B. Statement of Grounds

The upscheduling of hydrocodone combination products with hydrocodone bitartrate at levels lower than 5 mg in strength would have numerous unintended consequences, including depriving vulnerable patient populations of access to critically-needed pain medications.

A February 1, 2013 letter submitted by 18 patient and healthcare groups[1] to FDA voicing concerns about the January 25, 2013 vote of the Drug Safety and Risk Management Advisory Committee in favor of rescheduling combination hydrocodone products into Schedule II illustrates the importance of pain medications to these vulnerable patient populations. *See* Letter from Various Patient and Healthcare Groups to FDA, Docket No. FDA-2012-N-0548, Feb. 1, 2013, *available at* http://www.nacds.org/pdfs/pr/2013/PCF_FDA_hydro.pdf. Moreover, the letter describes how rescheduling certain of these drugs into Schedule II will not curb misuse and

[1] These groups are: American Academy of Pain Management (AAPM); American Association of Nurse Assessment Coordination (AANAC); American Cancer Society Cancer Action Network (ACS CAN); American Society of Consultant Pharmacists (ASCP); Amputee Coalition; Carson Company, LLC; Citizen Advocacy Center (CAC); Interstitial Cystitis Association; Long Term Care Pharmacy Alliance (LTCPA); Massachusetts Pain Initiative; NADONA; National Association of Chain Drug Stores (NACDS); National Community Pharmacists Association (NCPA); National Fibromyalgia & Chronic Pain Association; National Hospice and Palliative Care Organization; Pain Treatment Topics; US Pain Foundation; and Wisconsin Pain Initiative.

abuse of pain medications,[2] but will reduce drastically patient access to such medications and cause grave harm to patients that depend on the medications. *Id.* In fact, Docket No. FDA-2012-N-0548 is replete with statements from the public expressing disagreement with the proposed upscheduling.

While medications containing hydrocodone in combination with other pain relievers are often prescribed for acute pain, these products also play a critical role in helping patients manage, for example, chronic cancer and non-cancer pain over time. In fact, such products are effective for a wide range of painful conditions and diseases, and often are the ones that allow patients to complete their disease-related treatments, sleep through the night, and generally continue to work and live as close to normal lives as possible.

Rescheduling these medications would have far-reaching unintended consequences, including depriving pain control for millions of Americans. It is important to note that, according to the Institute of Medicine, there are 100 million Americans living with *chronic* pain, which does not include Americans with acute pain annually estimated by the Centers for Disease Control and Prevention ("CDC") to be 46 million from surgery alone.

As the Agency knows, per DEA regulations, prescriptions for Schedule II medications cannot be transmitted by telephone or fax, nor can they be refilled. Accordingly, the upscheduling of hydrocodone combination products would require patients to see their doctor for office visits with greater frequency simply to refill a prescription. As FDA could imagine, such a policy change would impose heavy burdens – economic and otherwise – on patients, caregivers and the health care system, and would likely create a much greater chance that patients with legitimate clinical need would be unnecessarily forced to endure symptoms of pain for longer periods of time.

Before making a recommendation to HHS to upschedule certain hydrocodone combination products, the undersigned would ask the Agency to consider hospice patients in end-of-life situations and patients receiving palliative care, and the impact such a recommendation would have on these vulnerable populations. Particularly for those terminal patients who wish to live out their remaining days at home, the upscheduling of critical pain-management drugs, like hydrocodone combination products, would be incredibly burdensome at a time when they have decided to gracefully accept the finality of their diseases without additional physician intervention.

This request to keep the lowest strength products, those less than 5 mg in strength, as Schedule III products strikes an important public policy balance by protecting vulnerable patient populations which rely on such medications without sacrificing the ability of DEA to target

[2] For example, despite being a Schedule II medication, oxycodone is one of the most heavily abused medications in the United States. Accordingly, it is hard to imagine that upscheduling hydrocodone products with hydrocodone bitartrate at less than 5 mg in strength into Schedule II would curb misuse and abuse of such products.

enforcement of drug products likely to be abused (*i.e.*, products in 5 mg strength and above). We note also that the consideration of these public health matters comports with the criteria in 21 U.S.C. § 811 that FDA, HHS and DEA are statutorily-required to consider when making a controlled substances scheduling determination. Accordingly, and for the reasons explained above, the undersigned respectfully requests that the Commissioner of Food and Drugs refrain from submitting recommendations to HHS to reclassify hydrocodone combination products lower than 5 mg in strength into the list of Schedule II drugs.

C. Environmental Impact

The petitioner requests a categorical exclusion from the requirement of preparing an environmental assessment. As provided in 21 C.F.R. § 25.31, neither an environmental assessment nor an environmental impact statement is required. To the best of the petitioner's knowledge, no extraordinary circumstances exist that may significantly affect the human environment as discussed under 21 C.F.R. § 25.21.

D. Economic Impact

As provided in 21 C.F.R. § 10.30(b), the petitioner agrees to submit economic impact information only if requested by the Commissioner of Food and Drugs following review of the petition.

E. Certification

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.

Sincerely,

Rebecca L. Dandeker

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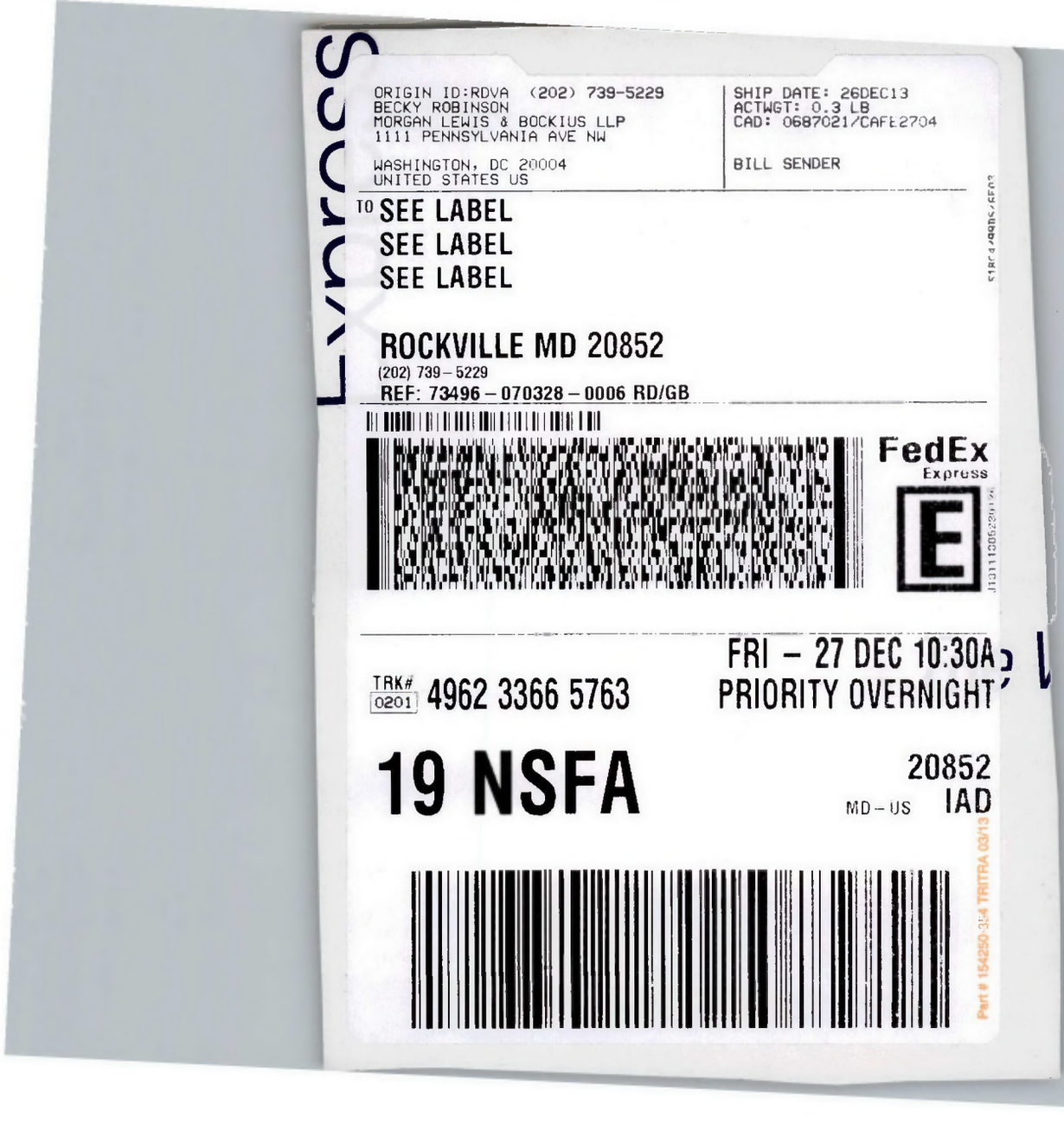

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