Docket

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

JAN 18 2013

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Mr. Harold Peiser
President, Peiser & Associates, Inc.
P.O. Box 774
Palm Harbor, FL 34682

Re: Docket No. FDA-2006-P-0343

Dear Mr. Peiser:

This responds to the citizen petition from Peiser & Associates[1] received August 7, 2006 (Petition),[2] in which Dr. Peiser requested that the Food and Drug Administration (FDA or Agency) follow the requirements of the Drug Listing Act (DLA) (Petition at 2). The Petition alleges that the DLA requires the Agency to list all human and veterinary drug products[3] in the National Drug Code (NDC) directory (Petition at 2), and, therefore, we understand the Petition to request that FDA include all human and veterinary drug products[4] in the NDC Directory. We have considered the Petition carefully, and for the reasons that follow, the Petition is granted in part and denied in part.

I. BACKGROUND

In 1967, acting on a Presidential directive, the Secretary of the Department of Health, Education, and Welfare (currently the Department of Health and Human Services) appointed a task force on prescription drugs to study problems associated with prescription drug reimbursement in government-supported health programs. The task force concluded that because computer processing of claims must be an integral part of such programs, there was an urgent need for a standardized drug identification or coding system that could be used in computerized systems. The task force also found that a standardized coding system was needed for drug manufacturers, re-packers, wholesalers,

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[1] This citizen petition was signed by Dr. Eugene Peiser in his capacity as President of Peiser & Associates, Inc. You are receiving this response as his successor.

[2] The Petition originally was assigned Docket No. 2006P-0310. This number has been changed to FDA-2006-P-0343, as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

[3] The Petition uses both "drug product(s)" and "drug(s)" when referring to the articles the Petition asserts are required to be listed in the NDC directory. *See, e.g.*, Petition at 3. The two terms are not necessarily interchangeable: the former, although not explicitly defined in the FD&C Act or the NDC-related regulations, is more commonly used to refer to a finished product (*see, e.g.*, 21 CFR 201.25(c)(1); 21 CFR. 207.25(c); section 510(j) of the FD&C Act), while the latter is broader (*see, e.g.*, section 201(g)(1) of the FD&C Act). However, out of an abundance of caution, we have interpreted the Petition's use of the word "drug product" in the Petition to refer to "drugs," more broadly.

[4] *See* n. 3, *supra.*

and others to facilitate the processing of transactions that occur as a product moves through routine commercial channels.

The Department of Health, Education, and Welfare assigned the task of developing and operating the NDC system to FDA. In 1967 and 1968, FDA held meetings with representatives of government agencies and the private sector to develop a voluntary coding system. In the *Federal Register* of July 2, 1969,[5] FDA announced the NDC system to provide "an identification system in computer language to permit automated processing of drug data by Government agencies, drug manufacturers and distributors, hospitals, and insurance companies." The system consisted of a nine-character NDC composed of the Labeler Identity Code to be assigned by FDA, and the Drug Product Identity Code and Trade Package Identity Code to be assigned by drug establishments within certain parameters defined by FDA. Participation in the system was voluntary and initially included establishments that manufactured and labeled, or repacked and labeled, drug products. In the July 1969 *Federal Register* notice, FDA stated that after the NDC numbers had been assigned, an NDC directory would be published to provide a listing of drug products and their NDC designations. The first edition of the NDC directory was published in 1969 and included more than 12,000 prescription and over-the-counter (OTC) drugs. In the *Federal Register* of January 1, 1971,[6] FDA extended participation in the system to distributors who marketed drug products in interstate commerce under their own name (label) and through multiple wholesale outlets and/or five or more retail outlets.

The Drug Listing Act of 1972[7] required registered establishments to list all drugs that they manufacture, prepare, propagate, compound, or process for commercial distribution, and it authorized FDA to assign a "listing number" to each drug or class of drugs that was listed. This authorization was codified in section 510(e) of the Federal Food, Drug, & Cosmetic Act (FD&C Act):

> The Secretary may assign a registration number to any person or any establishment registered in accordance with this section. The Secretary may also assign a listing number to each drug or class of drugs listed under subsection (j). Any number assigned pursuant to the preceding sentence shall be the same as that assigned pursuant to the National Drug Code. [. . .]

By providing authority to prescribe a uniform system for drug identification, the Drug Listing Act, in effect, authorized FDA to make participation in the NDC number system mandatory—and the Agency did so in its regulations.[8] In addition, by using the word *drug*, the Drug Listing Act extended the NDC number system to OTC drugs and animal drugs (because both are "drugs" under the FD&C Act and are listed under section 510(j) of the FD&C Act). In the Food and Drug Administration Amendments Act of 2007

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[5] *See* 34 FR 11157.

[6] *See* 36 FR 27.

[7] Public Law 92-387, 86 Stat. 559 (1972).

[8] *See* 21 CFR 207.35(b) ("Using the National Drug Code (NDC) numbering system, FDA assigns a drug listing number to each drug or class of drugs listed as follows . . .").

(FDAAA),[9] Congress amended section 510 of the FD&C Act to add section 510(p), which requires that all registrations and listings under section 510 be submitted electronically unless the Secretary grants a request to waive electronic submission.

II. DISCUSSION

The Petition states that its purpose is "[t]o compel the Agency to follow the requirements of the Drug Listing Act of 1972" (Petition at 2). In particular, it states that "[t]he [FD&C] Act requires the listing of ALL human and veterinary drug products"[10] (Petition at 2). FDA disagrees with both the Petition's characterization of the Drug Listing Act of 1972 and its assertion that the Agency is not following the law.

The Petition correctly states that the DLA authorized the mandatory submission to FDA of certain information on commercially distributed drugs, and that the DLA enabled the expansion of the NDC system to include human over-the-counter (OTC) drugs and veterinary drugs in addition to prescription drugs (*see* Petition at 3). However, neither the DLA nor any of FDA's associated regulations[11] requires that each of these drug listings be included in the NDC Directory itself.[12] In fact, no statute or regulation requires FDA to publish the NDC Directory at all.

To the extent it is feasible to do so, however, FDA is working to increase the number of human and animal drugs it lists in the NDC directory. Section 510(p) of the FD&C Act — mandating that registrations and listings be sent to the Secretary electronically, unless a waiver has been granted — has aided in achieving this goal, because electronic data is easier to transfer to an electronic directory than data submitted on paper. In addition, the Agency is working to amend the regulations in section 207 of title 21, Code of Federal Regulations, which govern entity registration and drug listing. These efforts include the intended finalization of the proposed rule "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs," which was published in the August 29, 2006, *Federal Register*.[13]

In sum, although it is FDA's goal to include as many human and animal drug products as possible in the NDC directory, the Agency is not required by law to include all of them. Therefore, the Agency is not in violation of its legal obligations — nor, for reasons including those described above, will it be able to ensure the future listing of every single human and animal drug that has been registered.

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[9] Public Law 110-85 (2007).

[10] *See* n. 3, *supra.*

[11] *See* 21 CFR Part 207.

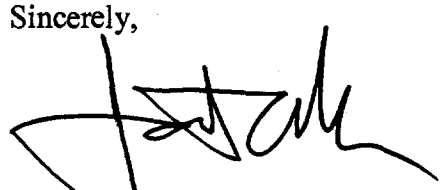
[12] Section 510(f) of the FD&C Act states that "[t]he Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section," but the registrations in question are those of the companies who are required to register, not the drugs they manufacture or process. The NDC Directory contains drug listings, not company registrations.

[13] *See* 71 FR 51276 *et seq.*

III. CONCLUSION

After careful consideration, and in light of the foregoing, the Petition is granted in part and denied in part. The request that FDA comply with the Drug Listing Act of 1972 is granted, because, as discussed above, the Agency already is in compliance with this law. The request that FDA list all human and veterinary drugs in the NDC directory as part of this compliance is denied. Please be assured, however, that FDA appreciates Peiser & Associates, Inc.'s desire to include all appropriately listed drugs in the NDC directory and will continue its efforts to provide information to the public to the extent possible.

Sincerely,



Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research