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January 26, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0403

Dear Sir/Madam:

On behalf of clients distributing medical foods, Hyman, Phelps & McNamara, P.C., (HPM) submits these comments on the Food and Drug Administration's (FDA's) August 29, 2006, proposed rule to amend its regulations governing drug establishment registration and drug listing. 71 Fed. Reg. 51276.

FDA is proposing to overhaul its drug registration and listing regulations, in pertinent part, to streamline the listing and registration process by changing it to an electronic system. Id. at 51294. In addition, FDA is proposing to assign NDC numbers prospectively for products that have not been previously assigned NDC numbers. Id. at 51296. FDA believes that this will give the agency better control over the numbers and

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ensure that the numbers are used properly. Id. FDA is also proposing to prohibit products “not subject to the drug listing requirements of part 207, such as dietary supplements and medical devices,” from bearing an NDC number. Id. at 51305 (proposed 21 C.F.R. § 207.37(d)). FDA has concerns that the use of NDC numbers on these products “can confuse drug databases or lead to inappropriate reimbursements.” Id. at 51296. FDA believes that “a human dietary supplement that bears an NDC number [is] misbranded under 21 U.S.C. 343(a)(1), which provides that a food is misbranded if its labeling is false or misleading in any particular.” Id. at 51305.

Medical foods are also not technically subject to the drug listing requirements of Part 207. Some distributors of such products do register and list them in order to obtain NDC numbers, which are a critical component of the current third-party payer reimbursement system. Therefore, FDA’s proposal to prohibit NDC numbers on dietary supplements and medical devices would also adversely affect medical foods.

We applaud FDA’s efforts to improve the drug registration and listing process as well as the process for tracking NDC numbers by converting it to an electronic system. However, we have serious concerns about FDA’s proposal to assign new NDC numbers prospectively and to prohibit products such as medical foods from bearing NDC numbers. Such a prohibition would diminish access to these extremely beneficial products by patients and their prescribing physicians. It would also have a very serious economic impact on small businesses by causing a major loss of business and jobs. FDA should factor into its

economic analysis the costs that its proposal will have on medical food companies and the consumers who use them, and the negative public health consequences to consumers who lose access to these products. We address each of these concerns in turn.

I. NDC Number Assignment Should Be Completed By Companies, Not FDA

FDA is proposing to assign NDC numbers prospectively for several reasons, all of which can be addressed using narrower means. In the proposal, FDA notes that “current regulations ... permit [companies] to re-use ... product codes under certain circumstances” and that “under current regulations, it is difficult for FDA to control the practice of a manufacturer, repacker, or relabeler making changes to use the same NDC number despite these changes.” Id. at 51296. FDA also notes that the product and package codes are not always assigned properly and that some electronic systems have trouble distinguishing two NDC numbers because of the variability in the length of the codes. However, FDA’s assignment of NDC numbers would disrupt current company operations by requiring companies to unnecessarily wait for the NDC assignment and, at the same time, it would unduly burden FDA.

Furthermore, FDA can address the concerns it has with companies assigning their own NDC numbers by changing its regulations to prohibit companies from engaging in the practices noted above and by issuing guidance that clearly explains how these codes must be structured. By providing further guidance and using its current enforcement tools, FDA

can achieve the same goals but without the undue administrative burden or hardship on industry that FDA's proposal would have.

II. FDA Should Permit Medical Foods to Bear NDC Numbers

Before explaining why medical foods should be able to bear NDC numbers, we first provide some background information on these products.

A. Background Information on Medical Foods

Products now regarded as medical foods were regulated as drugs by FDA until about 1972, when FDA began to regard them as a subcategory of foods for special dietary use. See, e.g., Regulation of Medical Foods; Advance Notice of Public Rulemaking, 61 Fed. Reg. 60661, 60662 (Nov. 29, 1996) (the "ANPR")¹; FDA Compliance Program on Medical Foods – Import and Domestic, CP 7321.002, Part I, page 2 (1998). The legal category was finally recognized by Congress in 1988 in the Orphan Drug Amendments, rather than the Federal Food, Drug, and Cosmetic Act (FDC Act). That law states:

The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of

¹ This ANPR was formally withdrawn by FDA. 69 Fed. Reg. 68831, 68838 (Nov. 26, 2004). The notice stated, however: "FDA believes the basic principles described in the ANPRM provide an appropriate framework for understanding the regulatory paradigm governing medical foods." Id. at 68834.

a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

21 U.S.C. § 360ee(b)(3). That definition was subsequently incorporated into the FDC Act by the Nutrition Labeling and Education Act of 1990 (“NLEA”). Pub. L. 101-535, 104 Stat. 2353, 2357. See FDC Act § 403(q)(5)(A)(iv) (exempting medical foods from nutrition labeling) and § 403(r)(5)(A) (exempting medical foods from regulations on nutrient content and health claims).

Although medical foods are no longer regulated as drugs, they are “intended for the specific dietary management of a disease or condition,” which FDA interprets to mean “that Congress intended these foods to be an integral part of the clinical treatment of patients.” 61 Fed. Reg. at 60668. Thus, patients with certain diseases or health conditions rely on medical foods as part of their treatment regimen, and, accordingly, many medical foods are reimbursed either by state Medicaid agencies or private health insurance programs.

B. NDC Numbers Are Necessary For Medical Food Reimbursement

In the proposal, FDA acknowledged that “NDC numbers were originally intended 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.’” 71 Fed. Reg. at 51295 (quoting 34 Fed. Reg. 11157 (July 2,

1969)). NDC numbers are used for this same purpose today because reimbursement systems are designed to recognize numbers in the NDC format. It is for this reason that, for many years, medical food companies have been obtaining labeler codes from FDA by registering and listing their products under Part 207 so that they can create NDC numbers for their products. We are not aware of any FDA objections to this practice. Indeed, FDA's own regulation states that "[r]egistration and listing do not constitute an admission, or agreement, or determination that a product is a drug as defined in section 201(g) of the act." 21 C.F.R. § 207.20(e).

Nevertheless, FDA wants to prohibit non-drug products such as medical foods from bearing an NDC number because FDA believes the use of NDC numbers on non-drug products would misrepresent the nature of the products and possibly lead to inappropriate reimbursements. 71 Fed. Reg. at 51305. We disagree with this concern. Using the abbreviation "NDC" before the number would not necessarily suggest that the product is a drug, no more than the "Rx" symbol on a dietary supplement would necessarily suggest that the dietary supplement is a drug or treats a disease. See Final Rule; Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000, 1022 (Jan. 6, 2000) ("Although [the word prescription and its abbreviation Rx] imply that the product is a prescription drug, some prescription drugs are intended for nondisease conditions. Therefore, if nothing else in the labeling [of a dietary supplement] suggests a disease use, the agency will not

consider the use of ‘prescription’ or ‘Rx’ to be an implied disease claim.”). Thus, any concern that the use of NDC numbers on medical foods would misrepresent the nature of the foods is unfounded.

There is another solution to FDA’s concern that the prefix “NDC” would be viewed as misleading. Medical foods and other non-drug products could be required to bear only the numerical portion of the NDC number, without the prefix “NDC.” The listing of a series of numbers by itself certainly does not represent that the product is a drug.

Furthermore, whether medical foods are properly reimbursed is not a concern of FDA. Rather, it is the state Medicaid agencies and private health care companies that must ensure the products’ proper reimbursement.

If FDA prohibits medical foods from bearing NDC numbers, this will disrupt a reimbursement system that has worked well for many years and require that a new, separate system be developed to process the reimbursement of these products. Developing a new system would be time-consuming and costly, and FDA has not factored these costs into its economic impact analysis.

Under FDA’s proposal, without the costly development of a new system for reimbursement, consumers’ access to medical foods will be seriously disrupted. Without a mechanism to track medical food use, state Medicaid and private health insurance companies would be unable or unlikely to reimburse the products, and many consumers would not be able to obtain products so vital to their disease management, either because of

a lack of products to purchase, or the inability to afford the products. Thus, in addition to creating confusion and unnecessary paperwork, the proposal would also be to the detriment of consumers' health.

We plan to submit in the near future information regarding the state Medicaid/Medicare and private health insurance companies that now cover medical foods. FDA's proposal will likely impact these entities.

III. FDA Has Not Considered the Significant Economic Impact the Proposed Rule Will Have on Medical Food Manufacturers or Their Customers

In its analysis of economic impacts of the proposal rule, FDA indicated that the "proposed rule is not considered economically significant under Executive Order 12866" and "will not have a significant impact on a substantial number of small entities" under the Regulatory Flexibility Act." 71 Fed. Reg. at 51326. However, FDA omitted from these calculations not only the impact that the rule will have on packaging services, *id.* at 51337, but also the impact that the rule will have on medical food manufacturers and consumers who have their medical foods reimbursed by state Medicaid and private health insurance companies.

Executive Order 12866 defines "significant regulatory action" as a rule likely to "[h]ave an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the

environment, public health or safety, or State, local, or tribal governments or communities.” 58 Fed. Reg. 51735, 51736 (Oct. 4, 1993) (emphases added). For the reasons set forth in Parts I and II above, we believe FDA’s proposed rule will adversely affect in a material way medical food companies, consumers of medical foods, and state Medicaid and private health insurance companies. FDA has not determined the costs associated with the development of a new tracking system for the reimbursement of medical foods or how FDA’s proposal will disrupt the reimbursement of these foods for consumers. FDA needs to factor these items into its economic analysis.

Similarly, FDA has not accounted for the small business medical food companies that will be adversely impacted by the proposed rule. The medical food companies we represent qualify as small businesses and should therefore have been included in the Regulatory Flexibility Act analysis.

IV. Conclusion

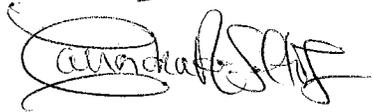
FDA’s proposed rule will have an enormous impact on industry, including a segment of the industry that FDA omitted in its analysis of the rule’s impact. Although FDA should update its drug registration and listing system to be electronic, FDA should

continue to allow companies to devise their own NDC numbers and permit medical foods to bear those numbers.

Respectfully submitted,



A. Wes Siegner, Jr.



Cassandra A. Soltis

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