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March 20, 2007

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

Re: Docket No. 2005N-0403
Supplement to Comments Submitted January 26, 2007

Dear Sir/Madam:

Hyman, Phelps & McNamara, P.C., (HPM) submits this supplement to its January 26, 2007, comments on the Food and Drug Administration's (FDA's) proposed rule to amend the drug establishment registration and drug listing regulations. 71 Fed. Reg. 51276 (August 29, 2006). This supplement contains data establishing that the proposed rule would have a serious adverse effect on a large number of patients who presently have coverage of medical foods under commercial health formularies, state Medicaid agencies, and other CMS-waivered programs.

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The attached Exhibits list the names of the commercial health formularies that cover certain medical foods, along with the number of patients that have access to the formulary, if available. The “Membership” column numbers show the number of patients covered for each commercial health formulary. Individuals may have overlapping coverage. For example, a person covered by Blue Cross Blue Shield could also be covered by their spouse’s health plan, and that person would be accounted for in both the Blue Cross Blue Shield plan and the other health plan.

The data in the Exhibits are from the fourth quarter 2006 and were obtained from Medimedia, a third party data provider that polls health plan coverage for various products. The following is an explanation of the data in the attached Exhibits.

- Exhibit 1: provides information on PPOs that cover medical foods, along with the number of lives covered by the particular plan.
- Exhibit 2: provides information on Medicare HMOs that cover medical foods, along with the number of lives covered by the particular plan.
- Exhibit 3: provides information on Pharmacy Benefit Managers that cover medical foods, along with the number of lives covered by their formularies.
- Exhibit 4: provides information on the Medicaid HMOs that cover medical foods, along with the number of lives covered by the particular plan.
- Exhibit 5: provides information on HMOs that cover medical foods, along with the number of lives covered by their formularies.

- Exhibit 6: provides information on state Medicaid Agencies that provide coverage to patients for Medical Food products.

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If you have any questions concerning this information, please let me know.

Sincerely,



A. Wes Siegner, Jr.


Cassandra A. Soltis

AWS/CAS/vam

Attachments