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

Re: Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Product Labeling; Medication Guide Requirements Docket Number FDA-2011-N-0902

Dear FDA PRA Staff,

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to comment upon the Food and Drug Administration's (FDA) notice, Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Product Labeling; Medication Guide Requirements ("notice"), announced in the Federal Register (80 Fed. Reg. 30688 (May 29, 2015)).

HDMA is the national association representing primary pharmaceutical distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. HDMA's membership includes 33 primary distribution companies — national, regional and specialty — that deliver prescription medicines and healthcare products throughout the country.

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HDMA Appreciates FDA's Correction of the Burden Hour Estimate on Wholesale Distributors

HDMA is appreciative of the inclusion of the burden hours estimate associated with 21 CFR 208.24(c) in the notice. On two previous occasions, HDMA had requested that FDA correct the burden hours for wholesale distributors who are required to distribute Medication Guides ("MedGuides"). In our comments submitted May 19, 2008, HDMA pointed out that the burden hour estimate for the wholesale distributor requirements under 21 CFR 208.24(c) was not included. In their subsequent notice addressing comments, FDA responded to this, stating:

"FDA agrees with the comments and is willing to include a burden estimate for §208.24(c)." 73 Fed. Reg. at 72056 (November 26, 2008)

Yet in 2012, a subsequent notice "Agency Information Collection Activities; Submission for OMB Review; Comment Request; Prescription Drug Product Labeling: Medication Guide Requirements." 77 FR 24961 (April 26, 2012) did not include a burden estimate associated with the requirements under 21 CFR 208.24(c). HDMA again submitted comments on March 25, 2012, noting the inconsistency and once more requesting inclusion of a burden estimate:

> "Though the requirements have not changed, four years later, FDA now concludes, without explanation, that the same requirements now impose no burden upon distributors. HDMA believes that FDA's 2008 response, with an update to reflect the more recent burden estimate, is the appropriate action for this information collection renewal."

We are pleased that FDA has now recognized the burden created by 21 CFR 208.24(c) and has corrected the omission by including an estimate in the notice. We appreciate your sensitivity to the burden that providing MedGuides places upon wholesale distributors as well as your efforts to understand and include those burden hours. HDMA would like to take this opportunity to express our gratitude to the FDA for listening to, and addressing, our concerns.

HDMA Neither Agrees Nor Disagrees With The Burden Requirements Under 21 CFR 208.24(c)

FDA provided the following burden estimates for 21 CFR 208.24(c):

Average burden per disclosure: 1.25 hours
Number of disclosures per respondent: 9,000
Number of respondents: 191
Total annual disclosures: 1,719,000

It is unclear how to interpret the terms included in the burden estimates and how those estimates were calculated. For example, it is not explained how the 1.25 hours was calculated as the average burden per disclosure or what the terms "respondent" or "disclosures per respondent" are intended to mean.

HDMA is uncertain whether "respondent" is intended to mean the total number of individual warehouses owned and operated by all wholesale distribution companies or the number of wholesale distribution companies (which have multiple warehouses).

Further, the term "disclosures per respondent" is unclear. For example, is it intended to include every instance that a MedGuide is provided with any drug in one year or simply if "disclosures per respondent" means the number of different types of drugs that a distributor would sell in a year for which a manufacturer was required to develop and supply a MedGuide? Moreover, the interpretation of "disclosures per respondent" would vary greatly depending on whether the word "respondent" is interpreted to mean individual warehouses or wholesale distribution companies.

Additionally, the calculation of the various burden hour estimates greatly impacts our interpretation of whether the burden hour estimate is accurate. For example, the 1.25 hours average burden per disclosure may not include the varying ways that wholesale distributors receive, and in turn distribute MedGuides with shipments. Typically, MedGuides are provided to wholesale distributors from the manufacturer by multiple methods. For example, they are sometimes included with the package insert alone, provided in the package with the drug, or can be a loose-leaf sheet(s) of paper and bulk shipped to the wholesale distributor as an altogether separate shipment or may be placed within the container in which the prescription product is shipped to the wholesale distributor. If the MedGuide is included on tear-off sheets or as loose-leaf paper, wholesale distributors are then responsible for coordinating the movement of those papers, taking significantly more time and consequently burden hours. We aren't certain if the 1.25 hour average burden estimate included all of these methods that wholesale distributors might take to include a MedGuide with a prescription.

Specifically, HDMA would like to request clarification of how FDA arrived at each of the numbers listed in the burden estimates and to clarify the definitions of "respondent", "average burden per respondent" and "disclosures per respondent". Without clarification, HDMA cannot comment on the accuracy of these estimates. Regardless, HDMA is highly appreciative of the inclusion of wholesale distributors in the burden estimate for MedGuides.

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HDMA thanks you for this opportunity to provide input on the information collection activities of FDA. If you have any questions or concerns, please contact me at 703-885-0240 or at aducca@hdmanet.org.

Respectfully submitted,

Anita T. Ducca
Senior Vice President, Regulatory Affairs