

UNITED STATES FOOD & DRUG ADMINISTRATION

Prescription Drug Advertising & Product Communications – 21 CFR 202

OMB Control No. 0910-0686

Request for Non-Substantive/Non-Material Change:

This information collection supports implementation of statutory and regulatory requirements that govern prescription drug advertisements. Currently, the information collection accounts for regulatory requirements as well as recommendations found in pertinent agency guidance. For efficiency of operations, we are requesting to move burden currently discussed and accounted for in OMB control no. 0910-0857 into this collection. We have modified the title of the collection to better characterize the scope of activity and are specifically requesting to include burden attendant to the guidance document “*Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities Questions and Answers*,” (June 2018) as itemized below:

Table 1.--Estimated Annual Third-Party Disclosure Burden					
Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved	430	10	4,500	20	90,000
Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved or cleared	236	10	2,360	20	47,200
Recommended information to be included when firms choose to disseminate information about unapproved products or	717	2	1,434	0.5	717
Follow-up information to payors regarding previously communicated about unapproved products or unapproved uses of approved or cleared products	359	2	718	2	1,436
TOTAL			9,012		139,353

Rather than include an individual line item, however, we have modified the entry “*IC recommended in FDA guidance*” by uploading the guidance document and adjusting our estimated burden upward by 9,012 responses and 139,555 hours. There have been no changes to referenced guidance document.

Submitted: June 2024