"Tobacco Product Establishment Registration and Listing"

(OMB Control Number–0910-0650)
Document Type Justification for No Material/Substantive Change
Change Request (83-C)

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The Food and Drug Administration (FDA) Center for Tobacco Products (CTP) is submitting this nonmaterial/non-substantive change request (83-C) for changes to an OMB approved information collection under OMB No. 0910-0650, "Tobacco Product Establishment Registration and Listing" This change is due to CTP switching from the current electronic registration and listing submissions system, known as eSubmitter, to a more robust and more efficient electronic registration and listing system known as FURLs. The information elements in eSubmitter and FURLS are identical, and FURLS offers the user an easier interface to enter that information.

The requested change to the current information collection burden and requirements under OMB No. 0910-0650 is to allow FDA to permit stakeholders of registration and listing information to have an easier way to submit that information. FDA thinks that the use of FURLs will reduce the overall burden on industry when submitting their registration and product listing submissions. The current system, eSubmitter, requires industry to download the eSubmitter software onto their computer and register for an Electronic Submissions Gateway (ESG) account, which can be a multi-week process, before they are able to submit information on FDA Form 3741. With FURLs, users may log in online instantly and begin their data entry. No software download or long wait is necessary.

The burden for entering new registration and product listing information under FURLs will likely be similar to that for eSubmitter. However, the burden for completing updates to this information will be greatly reduced. Reviewers estimate that 75% of labeling, advertising, and consumer information submitted during biannual product listing updates is duplicative. CTP has learned that the largest firms will often resubmit all labeling, advertising, and consumer information for up to 2 years in an effort to provide the most current snapshot of their marketing materials that may still be in distribution. In eSubmitter, companies resubmit these packages twice a year. In FURLs, industry can simply log in and delete any files that they believe are no longer current. They will no longer have to resubmit files every reporting period (June and December). A search of FDA's database shows that to date, 5,366 product listing s have been resubmitted when there was no change, and the use of FURLs will eliminate most of this duplicative resubmission of data.

FDA conservatively estimates that FURLs will reduce data-entry burden by approximately 35%. After a company submits the initial registration and product listing, they must annually update their registration (which is basically their address) and biannually submit changes to their product listing. Because FURLs will make it much easier to complete the biannual product

listing changes without the need to resubmit any files, FURLs should substantially reduce the burden on industry when filing these reports twice a year.

Original Burden: 200 annual responses x 3.75 hrs per response =750 total burden hours

Revised Burden due to use of FURLs: It is estimated that burden for the use of the FDA 3741 will decrease by 35%, or 200 annual responses x 2.44 hours per response = 488 total burden hours for this section.

The burden hours for the Tobacco Product Establishment Registration will be reduced from 750 to 488 hours for a reduction of 262 burden hours. The total burden for this ICR is now estimated to be 1,092. All other IC's remain unchanged.