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Docket No. FDA-2014-N-1009

AGENCY INFORMATION COLLECTION ACTIVITIES; PROPOSED COLLECTION; COMMENT REQUEST; INFORMATION REQUEST REGARDING PH OF SMOKELESS TOBACCO PRODUCTS

There are several places in which the FDA proposes to only request "final" data analyses and reports.

The FDA should request for "all" data and analysis rather than just "final" data and analysis. The industry has a documented history of manipulating analysis and presentation of results after completing preliminary analysis that produces unfavorable results. See, for example, The toxic effects of cigarette additives. Philip Morris' project mix reconsidered: an analysis of documents released through litigation. Wertz MS, Kyriss T, Paranjape S, Glantz SA. PLoS Med. 2011 Dec;8(12):e1001145. doi: 10.1371/journal.pmed.1001145. Epub 2011 Dec 20.

The FDA should request *all* versions, including drafts, as well as comments on those versions and reasons for changes made in subsequent versions.

There are several places where the FDA requests SAS datasets.

The FDA should not limit the datasets to SAS. The tobacco companies could avoid disclosure by simply using one of many other statistical packages. (The datasets for all the widely used programs can be cross converted using widely available inexpensive programs like StatTransfer.)

The FDA requests that documents available in the UCSF Legacy Tobacco Documents Library be identified by Bates number.

The FDA should require that documents be identified with the unique TID (or the full LTDL URL) rather than Bates number. Bates numbers are not unique; TIDs are. (If the FDA also wants the Bates number, that is ok, but unnecessary if the company provides the TID.)

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