

TABLE 1.—CHRONOLOGY OF THE OTC LAXATIVE DRUG PRODUCTS RULEMAKING PUBLICATIONS

Federal Register date and cite	Document
January 15, 1985 (50 FR 2124)	Proposed Rule (TFM) to Establish a Monograph for OTC Laxative Drug Products
October 1, 1986 (51 FR 35136)	TFM Amendment to Modify the Directions for Use and Dosages of OTC Bulk-Forming Laxatives
June 2, 1992 (57 FR 23174)	Notice to Reopen the Administrative Record to Accept Data and Information on Stimulant Laxative Active Ingredients Derived from Senna and Data on the Combination of Psyllium and Bran Active Ingredient
September 2, 1993 (58 FR 46589)	TFM Amendment to Include Docusate Salts, i.e., Docusate Calcium, Docusate Potassium, and Docusate Sodium, as Generally Recognized as Safe and Effective (GRASE) and Not Misbranded
March 31, 1994 (59 FR 15139)	TFM Amendment to Limit the OTC Drug Container Size for Sodium Phosphates Oral Solution to Not Greater Than 90 Milliliters (ml) (3 ounces (oz)) and to Add Warning
September 2, 1997 (62 FR 46223)	TFM Amendment to Reclassify the Stimulant Laxatives Danthron and Phenolphthalein from Category I (GRASE and Not Misbranded) to Category II (Not GRASE or Misbranded)
May 21, 1998 (63 FR 27886)	TFM Amendment to Include Additional General and Professional Labeling for Oral and Rectal Sodium Phosphates Drug Products
June 19, 1998 (63 FR 33592)	TFM Amendment to Reclassify the Stimulant Laxative Ingredients Aloe, Bisacodyl, Cascara Sagrada, and Senna Preparations from Proposed Category I to Category III (More Data Needed)
December 9, 1998 (63 FR 67817)	Notice of Withdrawal of Proposed TFM Amendment for Additional Professional Labeling for Oral and Rectal Sodium Phosphates Drug Products with Intent to Repropose
August 5, 2003 (68 FR 46133)	TFM Amendment to Reclassify the Bulk-Forming Laxative Psyllium Ingredients (Psyllium (Hemi-Cellulose), Psyllium Hydrophilic Mucilloid, Psyllium Seed, Psyllium Seed (Blond), Psyllium Seed Husks, Plantago Ovata Husks, and Plantago Seed)) in a Granular Dosage Form From Proposed Category I to Category II

Under § 330.10(a)(7)(v), new data and information submitted after the administrative record closed, before the establishment of a final monograph (FM), are considered a petition to amend the monograph and are to be considered only after a FM has been published unless FDA finds that good cause has been shown that warrants earlier consideration. Further, under § 330.10(a)(10)(ii), FDA shall make all decisions and issue all orders under § 330.10 in the FM solely on the basis of the administrative record and shall not consider data or information not

included as part of the administrative record.

FDA has received new data and information submitted to the rulemaking for OTC laxative drug products after the administrative record closed on the various dates after the TFM amendments listed in table 1 of this document (excluding August 5, 2003, for which the administrative record remains open until November 3, 2003). In some cases, interested persons submitted a petition to reopen the record. In other cases, they submitted new data and information to the

Division of Dockets Management as comments on the amended TFM. A number of the petitions and comments submitted to the amended TFM contain new data and information.

FDA has previously answered a number of these petitions (Refs. 1 through 7), and its response has been a final action on the petition. Thus, the current reopening of the administrative record does not include further comment on or consideration of the issues in these petitions. A summary of these petitions is included in table 2 of this document.

TABLE 2.—SUMMARY OF CITIZEN PETITIONS ON WHICH FDA HAS TAKEN FINAL ACTION

Docket code	Date of letter	Action	Subject
PDN14	June 4, 1996	Denial of CP18	Magnesium Citrate in Other Dosage Forms
PDN4	August 22, 1997	Denial of CP14	Two 45 Milliliter Doses of Sodium Phosphates Oral Solution 10 to 12 Hours Apart as a Bowel Cleansing System