this section do not exist or have been waived.

b. By adding new § 184.1763, to read as follows:

§ 184.1763 Sodium hydroxide.

(a) Sodium hydroxide (NaOH, CAS Reg. No. 1310–73–2) is referred to as sodium hydrate, soda lye, caustic soda, white caustic, and lye. The empirical formula is NaOH. Sodium hydroxide is prepared commercially by the electrolysis of sodium chloride solution and also by reacting calcium hydroxide with sodium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing conditions of use:

(1) The ingredient is used as a pH control agent as defined in § 170.3(o)(23) of this chapter and as a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Interested persons may on or before October 26, 1982, file with the Dockets Management Branch (address above) written comments regarding this tentative final regulation. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82–23519 Filed 8–26–82; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 341

[Docket No. 76N–052C]

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Over-the-Counter Anticholinergic Drug Products and Expectorant Drug Products; Notice of Proposed Rulemaking; Extension of Time for Comments, Objections, or Requests for Oral Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking; extension of period for comments, objections, or requests for oral hearing.

SUMMARY: The Food and Drug Administration (FDA) is extending the period for comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs for the notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) anticholinergic drug products and expectorant drug products. This action is being taken in response to a request to allow more time for interested persons to compile and submit data on existing studies on the effectiveness of guaifenesin, a Category III expectorant active ingredient, and to consult experts so that more informed comments may be submitted to FDA.

DATE: Written comments, objections, or requests for oral hearing by November 8, 1982.

ADDRESS: Written comments, objections, or requests for oral hearing to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 9, 1982 (47 FR 30002), FDA issued a notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of anticholinergic drug products and expectorant drug products for OTC human use. This notice of proposed rulemaking, which was based on the agency's evaluation of recommendations of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products, and public comments on those recommendations, is part of the ongoing review of OTC drug products conducted by the agency. Interested persons were given until September 7, 1982, to submit written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs on the notice of proposed rulemaking.

In response to the proposal, A. H. Robins Co. requested a 60-day extension of the time in which to submit comments, objections, or requests for oral hearing in order to allow adequate time for the company to compile and submit data on existing studies on the effectiveness of guaifenesin. These data include human and animal studies and a recent study conducted in Italy to demonstrate the effectiveness of guaifenesin in humans using the objective measurements recommended to A. H. Robins Co. by FDA. The company stated that, as soon as possible after the submission of these data, it plans to meet with FDA to determine if the agency considers these data satisfactory to prove the effectiveness of guaifenesin, or if additional studies will be required. The company added that if the agency concludes that the effectiveness of guaifenesin has not been proven, then it will file comments, objections, and a request for a hearing. The company stated that it plans to contact experts to evaluate the new data and the data previously submitted to FDA and pointed out the difficulty of contacting and consulting with such experts during the summer months.

FDA has carefully considered the request. The agency believes that the studies described in the request may be of assistance in establishing the effectiveness of guaifenesin as an OTC expectorant drug product and may obviate the need for further comments or objections in support of guaifenesin. FDA considers the request to be in the public interest because there currently are no Category I expectorant drug products. The agency therefore considers a general extension of 60 days to be appropriate. Accordingly, the period for comments, objections, or requests for oral hearing by any interested person is extended to November 8, 1982. The agency points out that this extension will not in any way extend the time for final action by the agency on the proposed regulation because the July 11, 1983 date for the submission of new data remains unchanged. Comments may be seen in the Dockets Management Branch, Food and Drug Administration (address above), between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 23, 1982.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-23672 Filed 8-26-82; 8:45 am]

BILLING CODE 4160-01-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[BC Docket No. 82-563; RM-4153]

FM Broadcast Station in Panama City, Florida; Proposed Changes in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: Action taken herein proposes the assignment of a fifth FM channel to Panama City, Florida, in response to a petition filed by WANM, Inc.

DATES: Comments must be filed on or before October 4, 1982, and reply comments on or before October 19, 1982.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Montrose H. Tyree, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Adopted: August 11, 1982.

Released: August 19, 1982.

In the matter of amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations. (Panama City, Florida); BC Docket No. 82-563, RM-4153; notice of proposed rule making.

1. A petition for rule making was filed on June 29, 1982, by WANM, Inc. ("petitioner"), proposing the assignment of Channel 292A to Panama City, Florida, as its fifth commercial FM allocation. Panama City is currently served by AM Stations WDLP and WWWQ; FM Stations WPAP-FM (Channel 223), WPFM (Channel 300), WGNE-FM (Channel 253) and Channel 278 (unapplied for); and noncommercial FM Station WKGC-FM (Channel 214C).

2. In support of the proposal, the petitioner submitted population data pertaining to Panama City. In view of the action taken in the *Second Report and Order*, in BC Docket 80-130, 90 F.C.C. 2d 88 (1982), this information is no longer relevant in a nonconflicting proposal. The petitioner has indicated that the proposed assignment meets the mileage separation requirements of the Commission's Rules and has stated its intention to apply for Channel 292A, if assigned to Panama City.

3. Since the proposed assignment could provide Panama City with an opportunity for its fifth commercial broadcast station, the Commission believes it appropriate to propose amending the FM Table of Assignments, § 73.202(b) of the Rules, as it relates to the following community:

City	Channel No.	
	Present	Proposed
Panama City, Fla.....	223, 253, 278, and 300.	223, 253, 278, 292A, and 300.

4. The Commission's authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein. NOTE: A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

5. Interested parties may file comments on or before October 4, 1982, and reply comments on or before October 19, 1982, and are advised to read the Appendix for the proper procedures.

6. The Commission has determined that the relevant provisions of the Regulatory Flexibility Act of 1980 do not apply to rule making proceedings to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules. See, *Certification that Sections 603 and 604 of the Regulatory Flexibility Act Do Not Apply to Rule Making to Amend §§ 73.202(b), 73.504 and 73.606(b) of the Commission's Rules*, 46 FR 11549, published February 9, 1981.

7. For further information concerning this proceeding, contact Montrose H. Tyree, Broadcast Bureau, (202) 632-7792. However, members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An *ex parte* contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission. Any comment which has not been served on the petitioner constitutes an *ex parte* presentation and shall not be considered in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment to which the reply is directed constitutes an *ex parte* presentation and shall not be considered in the proceeding.

(Secs. 4, 303, 48 stat., and amended, 1066, 1082, 47 U.S.C. 154, 303.)

Federal Communications Commission.

Roderick K. Porter,

Chief, Policy and Rules Division, Broadcast Bureau.

Attachment: Appendix.

Appendix

1. Pursuant to authority found in sections 4(i), 5(d)(1), 303 (g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.281(b)(6) and 0.204(b) of the Commission's Rules, IT IS PROPOSED TO AMEND the FM Table of Assignments, § 73.202(b) of the Commission's Rules and Regulations, as set forth in the *Notice of Proposed Rule Making* to which this Appendix is attached.

2. *Showings Required.* Comments are invited on the proposal(s) discussed in the *Notice of Proposed Rule Making* to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build a station promptly. Failure to file may lead to denial of the request.

3. *Cut-off Procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of the Commission's Rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this *Notice*, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

(c) The filing of a counterproposal may lead the Commission to assign a different channel than was requested for any of the communities involved.

4. *Comments and Reply Comments; Service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's Rules and Regulations, interested parties may file comments and reply comments on or before the dates set forth in the *Notice of Proposed Rule Making* to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s)