State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date[1]
Region III				
Pennsylvania				
Creekside, Borough of Indiana County	420499	Sept. 10, 1975, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Green, Township of Indiana County	421718	Feb. 18, 1976, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Morris, Township of Clearfield County	421529	Nov. 17, 1975, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Petrolia, Borough of Butler County	420221	Mar. 3, 1977, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Shelocta, Borough of Indiana County	420506	Oct. 7, 1975, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Walker, Township of Schuylkill County	422026	Mar. 19, 1975, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Weatherly, Borough of Carbon County	420255	May 28, 1975, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Region V				
Illinois:				
Dowell, Village of Jackson County	170875	Apr. 20, 1979, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Muddy, Village of Saline County	170599	July 10, 1975, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Wisconsin:				
Shawano, City of Shawano County	550421	Apr. 30, 1975, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Eleva, Village of Trempealeau County	550441	May 23, 1975, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Price County unincorporated areas	550343	Dec. 29, 1975, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Region VII				
Nebraska: Elk Creek, Village of Johnson County	310014	Sept. 25, 1979, Emerg.; Sept. 4, 1985, Reg.; Dec. 5, 1989, Susp	9-4-1985	Do.
Region X				
Oregon: Lake County unincorporated areas	410115	Mar. 3, 1975, Emerg.; Dec. 5, 1989, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Washington: Clallam County unincorporated areas	530021	Nov. 27, 1973, Emerg.; Nov. 5, 1980, Reg.; Dec. 5, 1989, Susp	12-5-1989	Do.
Region II				
New York: Lincoln, Town of Madison County	360405	Sept. 10, 1975, Emerg.; Sept. 4, 1985, Reg.; Dec. 15, 1989, Susp	12-15-1989	Dec. 15, 1989.
Region III				
Pennsylvania: Hyndman, Borough of Bedford County.	420121	Apr. 29, 1975, Emerg.; Dec. 15, 1989, Reg.; Dec. 15, 1989, Susp	12-15-1989	Do.
Virginia: Wise County unincorporated areas	510174	Oct. 30, 1974, Emerg.; Aug. 17, 1981, Reg.; Dec. 15, 1989, Susp	12-15-1989	Do.
Region IV				
Georgia: Fitzgerald, City of Ben Hill County	130007	Dec. 26, 1973, Emerg.; Dec. 15, 1989, Reg.; Dec. 15, 1989, Susp	12-15-1989	Do.
North Carolina:				
Moore County unincorporated areas	370164	June 4, 1975, Emerg.; Dec. 15, 1989, Reg.; Dec. 15, 1989, Susp	12-15-1989	Do.
Pinebluff, Town of Moore County	370337	Sept. 25, 1979 Emerg.; July. 17, 1986, Reg.; Dec. 15, 1989, Susp	7-17-1986	Do.
Swain County unincorporated areas	370227	Feb. 3, 1980, Emerg.; July. 17, 1986, Reg.; Dec. 15, 1989, Susp	12-15-1989	Do.
Region V				
Wisconsin: Park Falls, City of Price County	550344	Apr. 17, 1974, Emerg.; Dec. 15, 1989, Reg.; Dec. 15, 1989, Susp	12-15-1989	Do.
Ohio:				
Paulding County unincorporated areas	390777	Mar. 14, 1978, Emerg.; Dec. 5, 1989, Reg.; Dec. 15, 1989, Susp	12-5-1989	Dec. 5, 1989.
Waupaca, City of Waupaca County	550502	May 13, 1975, Emerg.; Aug. 3, 1989, Reg.; Dec. 15, 1989, Susp	12-5-1989	Dec. 15, 1989.
Region VII				
Kansas:				
Jackson County unincorporated areas	200147	July 15, 1983, Emerg.; Dec. 15, 1989, Reg.; Dec. 15, 1989, Susp	12-15-1989	Do.
Parsons, City of Labette County	200184	Oct. 3, 1974, Emerg.; July 16, 1979, Reg.; Dec. 15, 1989, Susp	12-5-1989	Do.
Missouri: Bolivar, City of Polk County	290299	July 24, 1975, Emerg.; June 16, 1988, Reg.; Dec. 15, 1989, Susp	12-15-1989	Do.

[1] Date certain Federal assistance no longer available in special flood hazard areas.

Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp—Suspension; Rein.-Reinstatement.

Issued: November 22, 1989.

Harold T. Duryee,

Administrator, Federal Insurance Administration.

[FR Doc. 89-28475 Filed 12-4-89; 8:45 am]

BILLING CODE 6718-21-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 2 and 90

[PR Docket No. 88-567; FCC 89-301]

Private Land Mobile Radio Service Stations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In response to a petition for rule making, 54 FR 1733 (January 17, 1989), the Commission adopted a Report and Order to permit applicants that file routine private land mobile station applications for facilities on shared frequencies to commence operations on a conditional basis during the application processing period upon the filing of their applications if they certify that certain conditions are satisfied. The satisfaction of these conditions indicates that the application can be routinely granted because it involves no special issues.

EFFECTIVE DATE: June 30, 1990.

FOR FURTHER INFORMATION CONTACT: Jerold Feldman, Land Mobile and Microwave Division, Private Radio Bureau, (202) 632-7125.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order, PR Docket No. 88-567, adopted on October 26, 1989 and released November 24, 1989. The full text of the Order is available for inspection and copying during normal business hours in the FCC Private Radio Bureau, Land Mobile and Microwave Division, Compliance Branch (room 5202), 2025 M Street, NW., Washington, DC. The complete text may also be purchased from the Commission's copy contractor, International Transcription Service, 2100

M Street, NW., Suite 140, Washington, DC 20037, (202) 857–3800.

Summary of Report and Order

1. In response to a January 1988 petition for rule making and a January 1989 notice of proposed rule making, the Commission issued a Report and Order adopting a system of conditional authority for applicants filing routine private land mobile station applications for certain shared frequencies. The conditional licensing procedure applies to applicants for shared frequencies in the bands below 470 MHz and in the one-way frequencies in the 929–930 MHz band. This procedure also encompasses applicants seeking to modify, assign or transfer existing stations in these frequency bands. Applicants for itinerant operations are also covered by this procedure.

2. This procedure permits applicants to commence conditional operations during the application processing period upon the filing of their applications with the Commission if they certify that certain conditions have been met. The satisfaction of these conditions indicates that the application involves no special issues and that the application will not be subject to challenge. These conditions are:

(1) That the proposed station is south of Line A or west of Line C and does not require Canadian coordination;

(2) That granting the application does not require rule waiver;

(3) That the proposed antenna structure has been previously studied by the Federal Aviation Administration and determined to pose no hazard to aviation safety as required by § 17.4 of the Commission's Rules; or that the proposed antenna or tower structure does not exceed 6.1 meters (20 feet) above ground level or above an existing man-made structure (other than an antenna structure), if the antenna or tower has not been previously studied by the Federal Aviation Administration and cleared by the Federal Communications Commission;

(4) That the applicant has determined that the proposed station will not significantly affect the environment as defined by § 1.1307 of the Commission's Rules;

(5) That the proposed station protects radio "quiet" zones and monitoring facilities as specified in § 90.177 of the Commission's Rules; and

(6) That the required frequency coordination procedures have been completed and that an application has been submitted to the Commission stating the frequency the applicant expects to use.

3. The above certifications will be contained on a new Conditional Temporary Authorization Form 572C. The executed original Form 572C must be retained by the applicant with the station records as evidence for conditional authority. Form 572C will contain express provisions warning the applicant that conditional authority may be terminated by the Commission at any time without a right to a hearing. In addition, the applicant will be required to acknowledge that it assumes all risks, including monetary loss due to equipment purchase, in the event conditional authority is terminated or the application is subsequently dismissed or denied.

4. Accordingly, *it is ordered*, that, pursuant to the authority of sections 4(i), 303(r), and 331(a) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 303(r) and 332(a), parts 1, 2 and 90 of the Commission's Rules, 47 CFR part 90, are amended effective June 30, 1990, as set forth below.

5. *It is further ordered*, that this proceeding is terminated.

List of Subjects

47 CFR Part 1

Administrative practice and procedure, Radio, Reporting and recordkeeping requirements.

47 CFR Part 2

Radio, Reporting and recordkeeping requirements.

47 CFR Part 90

Administrative practice and procedure, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

Rule Changes

Parts 1, 2, and 90 of the Commission's Rules (47 CFR Ch. I) are amended as follows:

PART 1—PRACTICE AND PROCEDURE

1. The authority citation for part 1 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended, 47 U.S.C. 154, 303; Implement 5 U.S.C. 552, unless otherwise noted.

2. Section 1.922 is amended by adding a new FCC form and title as follows:

§ 1.922 Forms to be used.

FCC form	Title
• • • • •	
572C	Conditional Temporary Authorization to Operate a Part 90 Radio Station.
• • • • •	

3. Section 1.925 is amended by redesignating current paragraph (1) as paragraph (i) and revising it and by adding new paragraph (i) to read as follows:

§ 1.925 Application for special temporary authorization, temporary permit or temporary operating authority.

* * * * *

(i) An applicant for an itinerant station license, an applicant for a new private land mobile radio station license in the frequency bands below 470 MHz and in the one-way paging 929–930 MHz band or an applicant seeking to modify or acquire through assignment or transfer an existing station below 470 MHz or in the one-way paging 929–930 MHz band may operate the proposed station during the pendency of its application for a period of up to 180 days under a conditional permit. Conditional operations may commence upon the filing of a properly completed formal application that complies with § 90.127 if the application, when frequency coordination is required, is accompanied by evidence of frequency coordination in accordance with §§ 90.175 and 90.176. Operation under such a permit is evidenced by retaining with the station records the original conditional licensing 572C Certification Form containing the certifications that satisfy the provisions of § 90.159(b).

(j) An applicant for a General Mobile Radio Service system license, sharing a multiple-licensed base station used as a mobile relay station, may operate the system for a period of 180 days, under a temporary permit, evidenced by a properly executed certification made on FCC Form 574–T, after mailing FCC Form 574 to the Commission.

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

1. The authority citation for part 2 continues to read as follows:

Authority: Secs. 4, 302, 303, 307, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 302, 303, 307, unless otherwise noted.

2. Section 2.302 is amended by adding a new class of station, composition of call sign, and call sign block to the table of call signs following the entry "Part 90 temporary permit" to read as follows:

§ 2.302 Call signs.

* * * * *

Class of station	Composition of call sign	Call sign blocks
*	*	*
Part 90 conditional permit.	2 letters, 7 digits...	WT plus local telephone number.
*	*	*

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

1. The authority citation for part 90 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat., as amended, 1066, 1082; 47 U.S.C. 154, 303, unless otherwise noted.

2. 47 CFR 90.159 is amended by revising its title and by designating the existing text of this rule section as paragraph (a) and adding new paragraphs (b), (c), (d), and (e) as follows:

§ 90.159 Temporary and conditional permits.

* * * * *

(b) An applicant proposing to operate a new private land mobile radio station or modify an existing station below 470 MHz or in the one-way paging 929–930 MHz band that is required to submit a frequency recommendation pursuant to § 90.175 (a) through (e) may operate the proposed station during the pendency of its application for a period of up to 180 days under a conditional permit upon the filing of a properly completed formal application that complies with § 90.127 if the application is accompanied by evidence of frequency coordination in accordance with §§ 90.175 and 90.176, and provided that the applicant certifies that the following conditions are satisfied:

(1) The proposed station location is south of Line A or west of Line C as defined in § 90.7.

(2) The proposed antenna structure has been previously studied by the Federal Aviation Administration and determined to pose no hazard to aviation safety as required by § 17.4 of the Commission's Rules; or the proposed antenna or tower structure does not exceed 6.1 meters (20 feet) above ground level or above an existing man-made structure (other than an antenna structure), if the antenna or tower has not been previously studied by the Federal Aviation Administration and cleared by the FCC.

(3) The grant of the application does not require a waiver of the Commission's Rules.

(4) The applicant has determined that the proposed facility will not significantly affect the environment as defined in § 1.1307.

(5) The applicant has determined that the proposed station affords the level of protection to radio "quiet" zones and monitoring facilities as specified in § 90.177.

(6) The applicant has submitted an application to the Commission stating the frequency the applicant intends to use and that the frequency coordination requirements specified in §§ 90.175 and 90.176 for selection and use of this frequency have been satisfied.

(c) An applicant proposing to operate an itinerant station, or, an applicant seeking the assignment of authorization or transfer of control of a license for an existing station operating below 470 MHz, or in the 929–930 MHz band, may operate the subject station during the pendency of the application for a period not to exceed 180 days under a conditional permit upon the filing of a properly completed formal application that complies with § 90.127. Conditional authority ceases immediately if the application is returned by the Commission because it is not acceptable for filing. All other categories of applications listed in § 90.175(f) that do not require evidence of frequency coordination are excluded from the provisions of this rule section.

(d) A conditional authorization pursuant to paragraphs (b) and (c) of this section is evidenced by retaining the original executed conditional licensing 572C Certification Form with the station records. Conditional authorization does not prejudice any action the Commission may take on the subject application. Conditional authority is accepted with the express understanding that such authority may be modified or cancelled by the Commission at any time without hearing if, in the Commission's discretion, the need for such action arises. Consistent with § 90.175(d), the applicant assumes all risks associated with operation under conditional authority, the termination or modification of conditional authority, or the subsequent dismissal or denial of its application. Authority reverts back to the original licensee if an assignee or transferee's conditional authority is cancelled.

(e) The transmissions of new stations operating pursuant to conditional authority shall be identified by a temporary call sign consisting of the prefix "WT" followed by the applicant's local seven digit business telephone number as provided in § 2.302. Transmissions by applicants for the modification, assignment of authorization or transfer of control of an existing station shall be identified by the station's call sign.

[FR Doc. 89–28208 Filed 12–4–89; 8:45 am]
BILLING CODE 6712–01–M

Proposed Rules

Federal Register
Vol. 54, No. 232
Tuesday, December 5, 1989

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR PART 349

[Docket No. 80N-145B]

Over-the-Counter Ophthalmic Drug Products for Emergency First Aid Use; Safety and Efficacy Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call-for-data for ingredients contained in eyewash drug products used for emergency first aid treatment of chemical burns of the eye(s). The agency will review the submitted data to determine whether these products are generally recognized as safe and effective for their labeled uses. This notice also describes the agency's general regulatory policy governing the marketing of over-the-counter (OTC) emergency first aid eyewash drug products during the pendency of this review. This request is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Data and information to be submitted by June 4, 1990.

ADDRESSES: Submissions should be sent to the Division of OTC Drug Evaluation (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In 1972, FDA established the OTC drug review to evaluate all drugs sold OTC. The final regulations providing for the OTC drug review under § 130.301 (recodified as § 330.10) were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). The agency appointed 17 advisory review panels to evaluate safety and effectiveness data of active ingredients found in OTC drug products. An advisory review panel, the Advisory Review Panel on OTC Ophthalmic Drug Products (Ophthalmic Panel), reviewed OTC ophthalmic drug products.

In its report on OTC ophthalmic drug products (published in the **Federal Register** of May 6, 1980; 45 FR 30002), the Ophthalmic Panel, in a general discussion of eyewashes, stated that eyewashes, eye lotions, and eye irrigating solutions are used to dilute or remove irritants such as foreign bodies, pollen, and noxious chemicals from the eye (45 FR 30046). The Panel mentioned that eyewashes, eye lotions, and eye irrigating solutions are not only used by consumers for cleaning and washing irritants from the eyes, but they are also used for the emergency flushing of chemicals or foreign bodies from the eye(s) in homes, places of work, first aid stations, clinics, and hospitals (45 FR 30047). The Panel recognized that these products are important components of first aid and emergency kits in industrial settings, clinics, and hospitals. In addition to their emergency first aid use, the Panel noted that irrigating fluids are used by medical personnel for irrigation following diagnostic procedures and for postoperative irrigation. Even though the Panel was aware of the existence and use of emergency first aid eyewashes and irrigating solutions, it did not consider these products further for these uses because no submissions were made by any company for these products or uses.

Following the publication of the Panel's report, no comments were submitted on the use of emergency first aid eyewashes or irrigating solutions. Accordingly, these products were not discussed in the tentative final monograph for OTC ophthalmic drug products that was published in the **Federal Register** of June 28, 1983 (48 FR 29788) or in the final rule that was published in the **Federal Register** of March 4, 1988 (53 FR 7076).

After the final rule was published, the agency received a request for an advisory opinion (Ref. 1) regarding the status of a product used for emergency first aid treatment of chemical burns of the eyes and the skin. The product was described as a sterile phosphate buffered solution containing sodium phosphate, U.S.P. and monobasic postassium phosphate, NF, preserved with edetate disodium, U.S.P. 1:2000 and benzalkonium chloride, U.S.P. 1:5000, for use immediately following a chemical burn to thoroughly flush the eyes and skin for the express purpose of removing the chemical irritant, and to relieve the discomfort and burning caused by the irritating chemical prior to seeking medical treatment. Noting that the final monograph for OTC ophthalmic drug products (21 CFR Part 349) is silent regarding the use of emergency first aid eyewashes for the treatment of chemical burns, the requester questioned how this product, which has a long marketing history, is to be regulated. The requester recommended that no regulatory action be considered until the problem has been resolved and a decision has been made by the agency as to how this type of product is to be regulated.

The agency is aware that a need exists for eyewash products for emergency first aid treatment of chemical burns (including acid and alkali burns). These products would be considered drugs just as eyewash products in the ophthalmic drug products final monograph are considered drugs. (See discussion of the drug status of eyewash products in comment 2 in the tentative final monograph at 48 FR 29789.)

A number of these eyewash products for emergency first aid treatment of chemical burns have been marketed prior to the effective date of the ophthalmic drug products final monograph. However, the agency currently has little data on which to make a determination as to the safety, effectiveness, and labeling of these products. The agency is aware that the majority of these products (1) are not intended to be marketed directly to individual consumers; (2) are often packaged in large volume containers not normally found at the retail level of distribution, especially for OTC ophthalmic drug products; (3) may be stored for long periods of time under different environmental conditions; (4) may be marketed in different types of containers and closure systems; and (5) may be used with nonplumbed, plumbed, self-contained emergency eyewash, or shower equipment/stations.

etc. The agency is not aware of all of the various labeling formats and labeling statements or the formulations of all the various eyewash products that are offered for emergency first aid ophthalmic use.

The agency is also aware that a number of these products are initially used without medical supervision like other OTC drug products. The agency believes these products could be regulated under the existing monograph for OTC ophthalmic drug products.

The agency is also aware that ophthalmic irrigating solutions are used by medical personnel for irrigating the eye(s) following diagnostic procedures and for postoperative irrigation. The agency believes that professional labeling for such uses of these products could be addressed in the existing monograph for OTC ophthalmic drug products.

Accordingly, FDA invites the submission of data, published and unpublished, and any other information pertinent to all active ingredients in eyewash drug products used for emergency first aid treatment of chemical burns of the eyes. These data and information will facilitate the agency's review and aid in its determination as to whether these OTC drugs for human use are generally recognized as safe and effective and not misbranded under their recommended conditions of use, and will provide all interested persons an opportunity to present for consideration the best data and information available to support the stated claims for these products. Any relevant data and information on eyewash ingredients that may have been submitted to earlier rulemakings should be resubmitted to facilitate the agency's review of this class of drug products. Even though the final monograph for OTC ophthalmic drug products (21 CFR Part 349) became effective on March 6, 1989, any data submitted pursuant to this call-for-data notice will be reviewed and addressed as part of the agency's ongoing review of all OTC drug products. If appropriate, as determined by the agency's review of any submitted data, the agency will proposed to amend the final monogram for OTC ophthalmic drug products to include eyewashes for emergency first aid treatment of chemical burns of the eye(s) and eye irrigating solutions for use following diagnostic procedures and for postoperative irrigation.

Under the agency's general regulatory policy governing the marketing of OTC drug products that do not have an approved new drug application (NDA) during the pendency of the OTC drug review, OTC drug products may be permitted to be marketed without the risk of regulatory action provided the following conditions are met:

(1) The product or similarly formulated and labeled products were marketed as OTC drugs at the inception of the OTC drug review on May 11, 1972, a date that was later extended to on or before December 4, 1975. (See 21 CFR 330.13.)

(2) Such product does not constitute a hazard to health.

(3) The product formulation is not regarded to be a prescription drug within the meaning of section 503(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(b)).

(4) It is an OTC drug and does not bear claims for serious disease conditions that require the attention and supervision of a licensed practitioner.

Emergency first aid eyewash products and eye irrigating solutions that do not meet the above criteria may not be marketed OTC pending evaluation of these products for the treatment of chemical burns and for irrigation of the eye(s) unless the product is the subject of an approved NDA.

It should be noted that, in the past, in order for a product to be eligible for the OTC drug review, the product or similarly formulated and labeled products had to be marketed as OTC drugs at the inception of the OTC drug review (May 11, 1972), a date that was later extended to on or before December 4, 1975. In addition, prescription drug products were eligible for the review, but they had to continue to be marketed on a prescription basis while data were being evaluated to ascertain whether the ingredient or combination of ingredients in the product had become generally recognized as safe and effective for OTC use.

The agency emphasizes that this current review is not intended to apply to new chemical entities that have not previously been marketed for OTC use regardless of the claims. Data on such products should be submitted to the agency for evaluation in a new drug application pursuant to 21 CFR part 314. Manufacturers should include any information that would establish that their product is not subject to action under the general regulatory policy described above as part of the data and information submitted in response to this call-for-data. If such information does not exist or is found to be inadequate, such products are at risk of regulatory action being instituted by the agency during the course of this review. To be considered in this review, eight copies of the data and information must be submitted, preferably bound, indexed, and on standard size paper (approximately 8½ by 11 inches). The agency suggests that all submissions be in the format described in 21 CFR 330.10(a)(2).

In accordance with § 330.10(a)(2), all submitted data on eyewash ingredients and claims for first aid relief of acid and alkali burns of the eye(s) will be handled as confidential by the agency. However, all the submitted information will be put on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, 30 days after publication of any proposed rules resulting from the review of the submitted material, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the act (21 U.S.C. 331(j)). At the time of publications, requests for confidentiality should be submitted to William E. Gilbertson, Center for Drug Evaluation and Research (HFD–210) (address above).

Data and information should be addressed to the Division of OTC Drug Evaluation (address above). Data submitted after the closing date of June 4, 1990, will not be considered except by petition pursuant to § 10.30 (21 CFR 10.30).

As noted above, some of these products are also labeled for use on the skin. The current call-for-data only applies to use of these products in the eyes. Use of these products on the skin will be addressed at a later date in a different OTC drug rulemaking.

Reference

(1) Comment No. AP, Docket No. 80N–0145, Dockets Management Branch.

Dated: November 23, 1989.

James S. Benson,

Acting Deputy Commissioner of Food and Drugs.

[FR Doc. 89–28316 Filed 12–4–89; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 540

Control, Custody, Care, Treatment and Instruction of Inmates; Contact With Media; Withdrawal of Proposed Rule

AGENCY: Bureau of Prisons, Justice.

ACTION: Proposed rule; withdrawal.

SUMMARY: By this document the Bureau of Prisons is withdrawing its proposed rule on Contact With the Media which