

RULES AND REGULATIONS

(Secs. 401, 701, 52 Stat. 1046, 1055-1056, as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 341, 371)

Dated: November 4, 1974.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.74-26183 Filed 11-7-74; 8:45 am]

SUBCHAPTER D—DRUGS FOR HUMAN USE
PART 330—OVER-THE-COUNTER (OTC)
HUMAN DRUGS WHICH ARE GENER-
ALLY RECOGNIZED AS SAFE AND EF-
FECTIVE AND NOT MISBRANDED

Contents and Time of Closing of
Administrative Record

The Commissioner of Food and Drugs issued a proposal, published in the FEDERAL REGISTER of June 4, 1974 (39 FR 19878), to amend § 330.10 (21 CFR 330.10) by adding a new paragraph (a) (10) designating (1) the contents of the administrative record on the basis of which the decision is made with respect to the status of an OTC drug product pursuant to the procedures governing the review and classification of OTC drug products, and (2) the point beyond which new factual information may no longer be submitted for consideration in the administrative process.

No comments were received in response to the proposal.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 321, 352, 355, 371) and the Administrative Procedure Act (secs. 4, 10, 60 Stat. 238 and 243 as amended; 5 U.S.C. 553, 702, 703, 704) and under authority delegated to the Commissioner (21 CFR 2.120), Part 330 is amended in § 330.10 by redesignating paragraph (a) (10) and (11) as (a) (11) and (12), and by adding a new paragraph (a) (10) to read as follows:

§ 330.10 Procedures for classifying OTC
drugs as generally recognized as safe
and effective and not misbranded,
and for establishing monographs.

(a) **Administrative record.** (i) All data and information to be considered in any proceeding pursuant to this section shall be submitted in response to the request for data and views pursuant to paragraph (a) (2) of this section or accepted by the panel during its deliberations pursuant to paragraph (a) (3) of this section or submitted to the Hearing Clerk as part of the comments during the 60-day period permitted pursuant to paragraph (a) (6) of this section. Thereafter, no new data or information may be submitted for inclusion in the administrative record of such proceeding except as provided in paragraph (a) (10) (ii) of this section.

(ii) New data or information not previously submitted for inclusion in the administrative record may be submitted for such inclusion only with a petition to the Commissioner requesting that the administrative record be reopened to in-

clude such material. The Commissioner may grant or deny such petition in his discretion. Any such petition shall demonstrate good cause why such material could not be obtained and submitted within the time specified in paragraph (a) (10) (i) of this section. If such a petition is denied, such material is properly submitted with a petition to amend the monograph pursuant to paragraph (a) (12) of this section.

(iii) The Commissioner shall make all decisions and issue all orders pursuant to this section solely on the basis of the administrative record, and shall not consider data or information not included as part of the administrative record.

(iv) The administrative record shall consist solely of the following material: All notices and orders published in the FEDERAL REGISTER, all data and views submitted in response to the request published pursuant to paragraph (a) (2) of this section or accepted by the panel during its deliberations pursuant to paragraph (a) (3) of this section, all minutes of panel meetings, the panel report(s), all comments and rebuttal comments submitted on the proposed monograph pursuant to paragraph (a) (6) of this section, all objections submitted on the tentative final monograph pursuant to paragraph (a) (7) of this section, the complete record of any oral public hearing conducted pursuant to paragraph (a) (8) of this section, all other comments requested at any time by the Commissioner, all data and information for which the Commissioner has reopened the administrative record, and all other material which the Commissioner includes in the administrative record as part of the basis for his decision.

Effective date. This order shall become effective on December 9, 1974.

(Secs. 201, 502, 505, 701, 52 Stat. 1040-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 321, 352, 355, 371 and secs. 4, 10, 60 Stat. 238 and 243 as amended; 5 U.S.C. 553, 702, 703, 704.)

Dated: October 31, 1974.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.74-26044 Filed 11-7-74; 8:45 am]

Title 47—Telecommunication
CHAPTER I—FEDERAL
COMMUNICATIONS COMMISSION
PART 0—COMMISSION
ORGANIZATION

Application for Verification of Operator
License

1. This Order is issued to delete obsolete reference to FCC Form 759—Application for Verification of Operator license—in § 0.483 (b) of the Commission's rules.

2. Because this is an editorial change, the prior notice and effective date provisions of the Administrative Procedure Act (5 U.S.C. 553) do not apply. Authority for this amendment appears in sections 4(i) and 303(r) of the Communications Act of 1934, as amended, and in

§ 0.231 (d) of the Commission's Rules and Regulations.

3. In view of the above, *it is ordered*, Effective November 15, 1974, that § 0.483 is amended as set forth in the attached Appendix.

(Secs. 4, 303, 48 Stat., as amended, 1066, 1082; 47 U.S.C. 154, 303.)

Adopted: November 1, 1974.

Released: November 1, 1974.

FEDERAL COMMUNICATIONS
COMMISSION,
[SEAL] **STANLEY MCKINLEY,**
Acting Executive Director.

APPENDIX

1. In § 0.483, paragraph (b) is amended to read as follows:

§ 0.483 Applications for amateur station
and operator license and/or commer-
cial operator license.

(b) Application for commercial operator license of a class for which examination is required, or for a verification card (FCC Form 758-F), shall be filed with a field office listed in § 0.121 (a) or (b) at which the applicant desires his application to be considered and acted upon, except that application for replacement or duplicate license of such class shall be filed with the office which issued the original license.

[FR Doc.74-26217 Filed 11-7-74; 8:45 am]

Title 43—Public Lands: Interior

CHAPTER II—BUREAU OF LAND MAN-
AGEMENT, DEPARTMENT OF THE IN-
TERIOR

APPENDIX—PUBLIC LAND ORDERS

[Public Land Order 5440]

[Wyoming 14982]

WYOMING

Withdrawal for Addition to Seedskafee
National Wildlife Refuge

By virtue of the authority vested in the President and pursuant to Executive Order No. 10355 of May 26, 1952 (17 FR 4831), it is ordered as follows:

Subject to valid existing rights, the following described public lands, which are under the jurisdiction of the Secretary of the Interior, are hereby withdrawn from all forms of appropriation under the public land laws, including the mining laws, 30 U.S.C. Ch. 2, but not from leasing under the mineral leasing laws, and reserved as an addition to, and for use in conjunction with those lands withdrawn by Public Land Order No. 4834 of May 20, 1970, for the Seedskafee National Wildlife Refuge:

SIXTH PRINCIPAL MERIDIAN

T. 23 N., R. 110 W.,
Sec. 32, lots 6, 7, 8, and 12.

The area described contains 90.50 acres in Sweetwater County.

JACK O. HORTON,
Assistant Secretary
of the Interior.

NOVEMBER 1, 1974.

[FR Doc.74-26241 Filed 11-7-74; 8:45 am]