

affirmation of the drugs' safety and effectiveness.

The Commissioner of Food and Drugs is amending Parts 510 and 558 (21 CFR Parts 510 and 558) to reflect these approvals.

(Sec. 512(1), 82 Stat. 347 (21 U.S.C. 360b(1))) and under authority delegated to the Commissioner (21 CFR 5.1)

Parts 510 and 558 are amended as follows:

1. In Part 510, § 510.600(c) (1) is amended to delete the entry for Hoechst-Roussel Pharmaceuticals, Inc., and to add a new entry alphabetically; and in paragraph (c) (2) to delete the firm name and address in entry No. 000039 and to add a new firm name and address, to read as follows:

§ 510.600 Names, addresses, and code numbers of sponsors of approved applications.

(c) * * *

(1) * * *

Firm name and address:

American Hoechst Corp., Agricultural Division, Route 202-206 North, Somerville, N.J. 08876..... 000039

(2) * * *

Drug listing No.:

000039..... American Hoechst Corp., Agricultural Division, Route 202-206 North, Somerville, N.J. 08876.

§ 558.15 [Amended]

2. In Part 558, § 558.15 *Antibiotic, nitrofurans, and sulfonamide drugs in the feed of animals* is amended in paragraph (g) (1) in the table in the column "Drug Sponsor" to delete the name Hoechst Pharmaceuticals and insert in its place the name American Hoechst Corp.

Effective date. This regulation becomes effective April 5, 1977.

(Sec. 512(1), 82 Stat. 347 (21 U.S.C. 360b(1)))

Dated: March 30, 1977.

C. D. HOUWELING,
Director, Bureau of
Veterinary Medicine.

[FR Doc. 77-10006 Filed 4-4-77; 8:45 am]

PART 510—NEW ANIMAL DRUGS PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Tylosin

AGENCY: Food and Drug Administration, HEW.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration approves a new animal drug application (NADA) for use of tylosin in swine feed.

EFFECTIVE DATE: April 5, 1977.

FOR FURTHER INFORMATION CONTACT:

Jack C. Taylor, Bureau of Veterinary Medicine (HFV-136), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, (301-443-5247).

SUPPLEMENTARY INFORMATION: The Food and Drug Administration approves an NADA (96-512V) filed by Dale Alley Co., P.O. Box 444, 222 Sylvan St., St. Joseph, Mo. 64502, proposing safe and effective use of a tylosin premix for the manufacture of complete swine feed for increased weight gain and improved feed efficiency.

The Commissioner of Food and Drugs is amending §§ 510.600 and 558.625 (21 CFR §§ 510.600 and 558.625) to reflect this approval.

In accordance with § 514.11(e) (2) (ii) (21 CFR § 514.11(e) (2) (ii)) of the animal drug regulations, a summary of the safety and effectiveness data and information submitted to support the approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday.

(Sec. 512(1), 82 Stat. 347 (21 U.S.C. 360b(1))), and under authority delegated to the Commissioner (21 CFR 5.1).

Parts 510 and 558 are amended as follows:

1. In Part 510, § 510.600 is amended by adding a new sponsor alphabetically to paragraph (c) (1) and numerically to paragraph (c) (2), to read as follows:

§ 510.600 Names, addresses, and code numbers of sponsors of approved applications.

(c) * * *

(1) * * *

Firm name and address:

Dale Alley Co., P.O. Box 444, 222 Sylvan St., St. Joseph, Mo. 64502..... 018083

(2) * * *

Drug listing No.:

018083..... Dale Alley Co., P.O. Box 444, 222 Sylvan St., St. Joseph, Mo. 64502.

2. In Part 558, § 558.625 is amended by adding paragraph (b) (50), to read as follows:

§ 558.625 Tylosin.

(b) * * *

(50) To 018083: 4 and 10 grams per pound; paragraph (f) (1) (vi) (a) of this section.

Effective date. This amendment becomes effective April 5, 1977.

(Sec. 512(1), 82 Stat. 347 (21 U.S.C. 360b(1)))

Dated: March 24, 1977.

C. D. VAN HOUWELING,
Director, Bureau of
Veterinary Medicine.

[FR Doc. 77-9866 Filed 4-4-77; 8:45 am]

PART 510—NEW ANIMAL DRUGS PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Zinc Bacitracin; Change of Sponsor

AGENCY: Food and Drug Administration, HEW.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration provides for a change in sponsor of a new animal drug application (NADA).

EFFECTIVE DATE: April 5, 1977.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Bureau of Veterinary Medicine (HFV-147), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, (301-443-4317).

SUPPLEMENTARY INFORMATION: The Food and Drug Administration approves a supplemental new animal drug application (NADA 98-452V) filed by A. L. Laboratories, Inc., a subsidiary of A/S Apothekernes Laboratorium for Specialpræparater, 452 Hudson Terrace, Englewood Cliffs, N.J. 07632, providing for the change in sponsor from Thompson-Hayward Chemical Co. to A. L. Laboratories, Inc. Thompson-Hayward Chemical Co. has also requested the change in sponsor. The approval is effective April 5, 1977.

The Commissioner of Food and Drugs is amending Parts 510 and 558 (21 CFR Parts 510, 558) to reflect this approval. He is also amending § 558.15 (21 CFR § 558.15) to delete reference to certain uses for which the firm does not have approvals.

The intercorporate transfer of the NADA does not involve changes in manufacturing, packaging, or quality control facilities. The approval has not required a reevaluation of the parent NADA and does not constitute a reaffirmation of the drug's safety and effectiveness.

(Sec. 512(1), 82 Stat. 347 (21 U.S.C. 360b(1))) and under authority delegated to the Commissioner (21 CFR 5.1)

Parts 510 and 558 are amended as follows:

§ 510.600 [Amended]

1. In Part 510, § 510.600 Names, addresses, and code numbers of sponsors of approved applications is amended in paragraph (c) (1) by deleting the entry

for "Thompson-Hayward Chemical Co." and in paragraph (c) (2) by deleting the entry for "011721."

2. Part 558 is amended:

a. In § 558.15, paragraph (g) (1) is amended in the second entry in the table in the column "Drug sponsor" to delete the firm name "Thompson-Hayward Chemical Co." and insert in its place the

new firm name "A. L. Laboratories, Inc." and to indicate approval for use in chickens, turkeys, pheasants, and quail only. The first two entries in the table read as follows:

§ 558.15 Antibiotic, nitrofur, and sulfonamide drugs in animal feeds.

(g) . . .	
(1) . . .	

Drug sponsor	Drug premix	Species	Use levels	Indications for use
IMC Chemical Group, Inc., Zinc bacitracin	Chickens, turkeys, swine, pheasants, quail, and cattle.	Sec. 558.78	Sec. 558.78	
A. L. Laboratories, Inc., do	Chickens, turkeys, pheasants, and quail.	do	do	Do.

§ 558.78 [Amended]

b. In § 558.78 Bacitracin, zinc, paragraph (a) (1) is amended by deleting the sponsor No. "011721" and inserting in its place the number "046573," and paragraph (e) (1) is amended in the table in items (i) and (ii) in the column headed "Sponsor" to delete the sponsor numbers "011721" and insert in their place the number "046573."

Effective date. These amendments become effective April 5, 1977.

(Sec. 512(1), 82 Stat. 347 (21 U.S.C. 360b(1)))

Dated: March 24, 1977.

C. D. VAN HOUWELING,
Director, Bureau of
Veterinary Medicine.

[FR Doc. 77-9875 Filed 4-4-77; 8:45 am]

SUBCHAPTER G—COSMETICS

[Docket No. 75N-0110]

PART 701—COSMETIC LABELING

Designation of Ingredients; Termination of Judicial Stay of Effective Date

AGENCY: Food and Drug Administration (FDA).

ACTION: Notification of termination of stay.

SUMMARY: This document announces that the United States Court of Appeals for the District of Columbia Circuit has upheld the validity of § 701.3 (21 CFR 701.3) that requires cosmetic labels to bear a declaration of ingredients, and has vacated the stay of the effective date for complying with the regulation in labeling packages.

DATES: The agency will allow affected persons until April 15, 1977, to comply with § 701.3 in labeling packages.

FOR FURTHER INFORMATION CONTACT:

Heinz J. Elermann, Bureau of Foods (HFF-440), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204. (202-245-1530).

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs issued a regulation, published in the

FEDERAL REGISTER of October 17, 1973 (38 FR 28912), requiring the declaration of ingredients on cosmetic labels; amendments to the regulation were published in the FEDERAL REGISTER of March 3, 1975 (40 FR 8918). In the FEDERAL REGISTER of May 30, 1975 (40 FR 23458), the Commissioner established the following effective dates for complying with the regulation as amended: "All labeling for cosmetic products ordered after May 31, 1976 and all cosmetic product packages labeled after November 30, 1976 shall comply with the requirements of § 701.3."

The Independent Cosmetic Manufacturers and Distributors (ICMAD) challenged the regulation in lawsuits brought in the United States District Court for the District of Columbia and the United States Court of Appeals for the District of Columbia (ICMAD v. Department of Health, Education, and Welfare, Civil Action No. 75-1845; ICMAD v. Mathews, Civil Action No. 76-1007). The lawsuit in the District Court was dismissed on jurisdictional grounds. On January 27, 1977, the Court of Appeals affirmed the dismissal by the District Court, and denied the petition for review in the lawsuit initiated in the Court of Appeals.

On November 24, 1976, the Court of Appeals granted a motion by ICMAD for a stay "of effective date" of the regulation until further order of the Court. The Court of Appeals, on March 14, 1977, vacated the stay of the effective date that it had previously ordered.

The Food and Drug Administration issued a notice in the FEDERAL REGISTER of December 7, 1976 (41 FR 53477) notifying interested persons of the stay and its effect. The stay by the Court of Appeals applied only to the November 30, 1976 effective date for labeling packages. The stay did not affect the May 31, 1976 effective date for complying with the requirement to declare ingredients in all labeling for cosmetics ordered after that date. Thus, this latter requirement continues in effect without change.

The November 30, 1976 effective date stayed by the Court of Appeals applied to packages labeled after that date. Because of the stay, labels not complying with § 701.3 that were ordered before May 31, 1976 could continue to be applied to cosmetic packages until the stay

ended. When the Court of Appeals terminated the stay on March 14, 1977, the requirement to comply with § 701.3 in labeling packages came into effect.

The Commissioner recognizes, however, that it may take some time for interested person to learn of the termination of the stay and to implement the necessary actions to comply. Accordingly, the Commissioner will not take regulatory action with respect to any noncompliance with the requirement in § 701.3 to declare cosmetic ingredients in labeling applied to packages before April 15, 1977. Since all labeling ordered after May 31, 1976 that can continue to be it is only labeling ordered on or before May 31, 1976 that can continue to be applied to packages until April 15, 1977 without being subject to regulatory action if the labeling fails to comply with § 701.3.

In accordance with the Commissioner's advice stated in the FEDERAL REGISTER of March 3, 1975, labeled packages in inventory bearing labeling ordered before May 31, 1976 may be used up at any time hereafter, whether or not the packages comply with § 701.3. This is not affected by the termination of the stay of the effective date for labeling packages.

(Secs. 5(c), 6(a), 80 Stat. 1298, 1299 (15 U.S.C. 1454, 1455)) (sec. 7101(e), 52 Stat. 1055-1056 as amended) (21 U.S.C. 371(e)) and under authority delegated to the Commissioner (21 CFR § 5.1.)

Dated: March 28, 1977.

JOSEPH P. HILE,
Associate Commissioner
for Compliance.

[FR Doc. 77-9715 Filed 3-29-77; 12:09 pm]

SUBCHAPTER J—RADIOLOGICAL HEALTH

[Docket No. 76N-0029]

PART 1002—RECORDS AND REPORTS

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

Submissions of Data and Reports; Dealer and Distributor Records; Certification and Identification Labels

AGENCY: Food and Drug Administration, HEW.

ACTION: Rule.

SUMMARY: This rule is amending the radiological health regulations: (1) To require under new § 1002.7 (21 CFR § 1002.7) that all written material submitted pursuant to Part 1002 conform to the current applicable electronic product reporting guide or instruction when such a guide or instruction has been issued by the Director, Bureau of Radiological Health; (2) to delete the requirement under §§ 1002.40 and 1002.41 (21 CFR §§ 1002.40 and 1002.41) that dealers and distributors notify the Bureau of their election to preserve their own records, and to eliminate inconsistencies in the language between the two sections; and (3) to require under §§ 1010.2 and 1010.3 (21 CFR §§ 1010.2 and 1010.3) that certification and identification labels or

tags be in the English language, except for certain abbreviations as currently described in § 1010.3(a)(1).

EFFECTIVE DATE: May 5, 1977.

FOR FURTHER INFORMATION CONTACT:

John Taschner, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, (301-443-3426).

SUPPLEMENTARY INFORMATION: In a notice proposing the subject amendments published in the *FEDERAL REGISTER* of March 30, 1976 (41 FR 13367), interested persons were given until June 1, 1976 to file written comments with the Hearing Clerk, FDA, regarding the proposal.

Six comments from manufacturers of electronic products subject to control under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.) addressed the proposed requirement that all written material submitted pursuant to Subchapter J shall conform to the reporting guide or instruction issued by the Bureau. The issues raised by these comments and the Commissioner's conclusions thereon are as follows:

1. Four comments objected to requiring adherence to current reporting guides in submitting reports and data to FDA. These comments argued that such a requirement, rather than being for the benefit of the manufacturer, is for the administrative convenience of FDA and would place an enormous burden and expense on the manufacturer. Such requirement, according to the comments, has no connection with limiting radiation exposure of the population, but would impose on the affected industry specific formats for maintaining test data and other documentation that may be in conflict with marketing protocols or the manufacturer's own rules and procedures. They also argued that the reporting guides are intended to aid communication of information submitted in response to regulatory requirements and should not become rigid rules requiring justification of any deviation.

The Commissioner believes that reporting guides are of benefit to manufacturers as well as FDA. They provide a consistent and uniform reporting format that affords greater assurance that an adequate report is prepared initially, thereby minimizing the need for costly and time consuming correspondence between FDA and the manufacturer. In the past, some manufacturers have submitted test data that were not pertinent to FDA's responsibility for ascertaining whether the manufacturer's quality control program did, in fact, assure that hazardous radiation would not be emitted from their electronic products. Reporting guides identify to the manufacturer the pertinent information required by FDA reporting regulations to fulfill its delegated responsibilities under the act and to make the manufacturer's reporting task easier. Thus, the reporting

guides are intended to reduce the burden and expense of reporting on the part of the manufacturer and to expedite the review of these reports by FDA.

The Commissioner does not intend to dictate to the affected manufacturers any specific format for maintaining their test data or other documentation concerning their electronic products. The amendment requires only that the necessary information be submitted to FDA in conformance with the applicable reporting guide or instruction. Thus, manufacturers may maintain their own records to conform to their own internal documentation standards and procedures.

The Commissioner also does not intend to require rigid adherence to the applicable reporting guide or instruction when it is not feasible or when it would be inappropriate to do so. To clarify this, § 1002.7 has been modified to permit a manufacturer to use an alternate format for that portion of the reporting guide considered to be inappropriate.

2. Three comments recommended that the reporting guides be submitted to the affected industry for review and comment before their being mandated.

The Commissioner has no objection to making the reporting guides available to the affected industry for their review and comment and in the future will do so to the extent possible. In addition, comments and suggestions for revision and improvement of the reporting guides will be solicited at the time of issuance.

3. One comment stated that if following the prescribed reporting guide or instruction is to become mandatory, FDA must make certain that the information called for is required by appropriate regulations and is within FDA's authority. The comment alleged that some items in the current FDA reporting guides have been viewed by manufacturers as being an expansion of the requirements of the particular standard or are outside the authority of FDA.

The Commissioner has authority under section 360A(b) of the act to require reports and information necessary to determine if the manufacturer is acting in compliance with the act and with an applicable standard. A reporting guide is intended to interpret the reporting regulations to obtain relevant and necessary information concerning electronic products and testing programs, whether or not these products are subject to performance standards. The reporting guide is not a mechanism for imposing additional performance requirements. However, an applicable performance standard is subject to interpretation and a reporting guide may, through language or construction, relate to an interpretation of a standard as well as the reporting regulations. A manufacturer who believes that any portion of a reporting guide is based upon an erroneous interpretation of a standard or reporting regulation may request an advisory opinion on the applicable portion of the regulation or submit written comments to FDA and request that the disputed portion of the reporting guide be reconsidered, modified, or deleted.

4. In the March 30, 1976 proposal, the requirement that material submitted pursuant to Subchapter J shall conform to the applicable reporting guide or instruction was contained in a new § 1000.14 (21 CFR 1000.14). It was originally intended that this requirement apply to the submission of all written material required by Subchapter J such as test data, initial and annual reports, reports of model changes, and exemption and variance requests. The Commissioner has since determined that this requirement need apply only to the material submitted pursuant to Part 1002, related to "Records and Reports." Therefore, the requirement has been transferred to new § 1002.7 Submission of data and reports.

5. The abbreviation exception to the amended requirement in § 1010.2 that certification labels and tags be in the English language is being moved to § 1010.3 to clarify the original intent that the English language requirement is applicable also to identification labels and tags.

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f) and under authority delegated to the Commissioner (21 CFR 5.1).)

Parts 1002 and 1010 are amended as follows:

1. In Part 1002:
 - a. By adding new § 1002.7 to read as follows:

§ 1002.7 Submission of data and reports.

All submissions such as reports, test data, product descriptions, and other information required by this part, or voluntarily submitted to the Director, Bureau of Radiological Health, shall be filed with the number of copies as prescribed by the Director, Bureau of Radiological Health, and shall be signed by the person making the submission.

(a) In addition to the requirements of this part, all material submitted to the Director, Bureau of Radiological Health, shall be submitted pursuant to the provisions of Part 20—Public Information, of this chapter.

(b) Where guides or instructions have been issued by the Director, Bureau of Radiological Health, for the submission of material required by this part such as test data, initial and annual reports, and reports of model changes, the material submitted shall conform to the applicable reporting guide or instruction to the extent that it is possible or appropriate to do so. Where it is not feasible or where it would not be appropriate to conform to any portion of a prescribed reporting guide or instruction, an alternate format for providing the information requested by that portion of the guide or instruction may be used provided the submitter of such information submits adequate explanation and justification for use of an alternate format. If the Director, Bureau of Radiological Health, determines that such justification is inadequate and that it is feasible or appropriate to conform to the prescribed reporting guide or instruction, he may require resubmission

of the information in conformance with the reporting guide or instruction.

b. By revising the section heading and paragraph (a) of § 1002.40 and by adding new paragraph (c) to read as follows:

§ 1002.40 Records to be obtained by dealers and distributors.

(a) Dealers and distributors of electronic products listed in § 1002.31(c), for which there are applicable Federal standards under this subchapter and for which the retail price is not less than \$50, shall obtain such information as is necessary to permit tracing of specific products to specific purchasers.

(c) The information obtained pursuant to this section shall be forwarded immediately to the appropriate manufacturer of the electronic product, or preserved as prescribed in § 1002.41.

c. By revising the section heading and paragraphs (a) (2) and (b) of § 1002.41 to read as follows:

§ 1002.41 Disposition of records obtained by dealers and distributors.

(a) * * *

(2) The dealer or distributor, upon making the election under paragraph (a) (1) of this section, promptly notifies the manufacturer of such election; such notification shall be in writing and shall identify the dealer or distributor and the electronic product or products for which the information is being accumulated and preserved.

(b) Every dealer or distributor who elects to hold and preserve information required pursuant to § 1002.40 shall preserve the information for a period of 5 years from the date of the sale, award, or lease of the product, or until the dealer or distributor discontinues dealing in, or distributing the product, whichever is sooner. If the dealer or distributor discontinues dealing in, or distributing the product, such information as obtained pursuant to § 1002.40 shall be furnished at that time, or before, to the manufacturer of the product.

2. In Part 1010:

a. By revising § 1010.2(b) to read as follows:

§ 1010.2 Certification.

(b) The certification shall be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use, unless the applicable standard prescribes some other manner of certification. All such labels or tags shall be in the English language.

b. By revising the introductory text of § 1010.3(a) to read as follows:

§ 1010.3 Identification.

(a) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall set forth the information specified in paragraph (a) (1) and (2) of this sec-

tion. This information shall be provided in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the applicable standard. Except for foreign equivalent abbreviations as authorized in paragraph (a) (1) of this section all such labels or tags shall be in the English language.

Effective date. These amendments shall be effective May 5, 1977.

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f).)

Dated: March 18, 1977.

JOSEPH P. HILE,
Associate Commissioner
for Compliance.

[FR Doc. 77-9878 Filed 4-4-77; 8:45 am]

Title 22—Foreign Relations
CHAPTER I—DEPARTMENT OF STATE
[Dept. Reg. 108.736]

PART 6a—PRIVACY ACT POLICIES AND PROCEDURES

Denial of Access; Amendment

On February 17, 1977 the Department of State published a notice of proposed rulemaking in the FEDERAL REGISTER (42 FR 9684) setting forth proposed regulations to implement the Privacy Act of 1974 (5 U.S.C. 552a). The proposed regulations established administrative procedures to appeal the Department's denial of access to records requested under the Privacy Act. Interested persons were given until March 21, 1977 to submit comments concerning the proposed regulations; no comments were received.

Accordingly, the amendments to Part 6a are adopted as set forth below.

Effective date: These amendments are effective April 1, 1977.

(Sec. 4 of the Act of May 26, 1949, as amended (63 Stat. 111; 22 U.S.C. 2658); Pub. L. 93-579, 88 Stat. 1897; 5 U.S.C. 552a.)

For the Secretary of State.

Dated: March 30, 1977.

CLAYTON E. McMANAWAY,
Acting Deputy Under Secretary
for Management.

1. Section 6a.7 is revised to read as follows:

§ 6a.7 Denial of access.

The decision to deny an individual access to his or her record shall be made by the Department official of a rank not below the Deputy Assistant Secretary or equivalent level who is responsible for the system of records involved. When an authorized official denies access to a record or portion thereof, the official will advise the individual of the denial in writing. The letter of denial shall cite the Privacy Act exemption(s) claimed and shall give the specific reasons therefor. The letter shall also state that the denial may be appealed to the Privacy Policy and Appeals Board and shall in-

clude a copy of the Department's regulations on appeals, § 6a.8.

§ 6a.8 Redesignated as § 6a.9.

2. The present § 6a.8 is renumbered as § 6a.9 and a new § 6a.8 is added to read as follows:

§ 6a.8 Appeals for denial of access.

(a) Review of an initial denial of access to a record under § 6a.7 may be requested by the individual who submitted the initial request for access. The review (hereinafter referred to as the appeal) must be in writing and should be sent by certified mail to the Chairman, Privacy Policy and Appeals Board, Department of State, Room 1239, 2201 C Street N.W., Washington, D.C. 20520. The appeal should be received within 60 days of the date the individual is informed of the Department's refusal to grant access to a record in whole or in part.

(b) The time for decision on the appeal begins on the date the appeal is received by the Chairman, Privacy Policy and Appeals Board. The appeal of a denial of access to records shall include any documentation, information and statements to support the individual's request for access and to refute the use of the exemption(s) cited in the Department's justification concerning the denial of access.

(c) The Chairman of the Privacy Policy and Appeals Board (Assistant Secretary of State for Administration) or his designee and at least two other members of the Board designated by him shall constitute a panel to consider and decide the appeal; there shall be a written record of the reasons for the final determination. The final determination will be made within 30 days (excluding Saturdays, Sundays, and legal public holidays), unless for good cause shown, the Chairman of the Privacy Policy and Appeals Board extends such determination beyond the 30-day period.

(d) When the final determination is to grant access to the record in accordance with the individual's request, the Chairman of the Privacy Policy and Appeals Board shall inform the office responsible for the record of its decision. The Board shall then request the Director, Foreign Affairs Document and Reference Center, to notify the individual in writing of the Board's decision to grant access and at the same time to inform the individual of the Department's regulations concerning access and identification, § 6a.4. The individual shall choose the means of access most convenient to him or her.

(e) When the final decision of the Board is to refuse to grant an individual access to a record, the Chairman of the Board shall advise the individual in writing:

(1) of the refusal to grant the appeal and the reasons therefor including the exemption(s) of the Privacy Act under which access is denied;

(2) of his or her right to seek judicial review of the Department's decision.

3. In the renumbered § 6a.9, paragraph (f) is revised to read as follows: