respectively, by revising the first sentence of newly redesignated paragraph (c)(4), and by revising paragraph (f)(1) to read as follows:

**§ 310.305 Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications.**

(a) *Scope.* FDA is requiring manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved new drug or abbreviated new drug application to establish and maintain records and make reports to FDA of all serious, unexpected adverse drug experiences associated with the use of their drug products.

* * * * *

(c) * * *

(4) To avoid unnecessary duplication in the submission of, and followup to, reports required in this section, a packer's or distributor's obligations may be met by submission of all reports of serious adverse drug experiences to the manufacturer of the drug product. * * *

* * * * *

(f) *Recordkeeping.* (1) Each manufacturer, packer, and distributor shall maintain for a period of 10 years records of all adverse drug experiences required under this section to be reported, including raw data and any correspondence relating to the adverse drug experiences, and the records required to be maintained under paragraph (c)(4) of this section.

* * * * *

## PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

3. The authority citation for 21 CFR part 314 continues to read as follows:

**Authority:** Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e).

4. Section 314.80 is amended by removing the definition for *Increased frequency* in paragraph (a), by removing paragraph (c)(1)(ii), by redesignating paragraphs (c)(1)(iii) and (c)(1)(iv) as paragraphs (c)(1)(ii) and (c)(1)(iii), respectively, by revising the first two sentences in the introductory text of newly redesignated paragraph (c)(1)(ii), by removing the last sentence in paragraph (d)(1), by revising paragraph (f)(1), and by revising the last sentence in paragraph (l) to read as follows:

**§ 314.80 Postmarketing reporting of adverse drug experiences.**

* * * * *

(c) * * *

(1) * * *

(ii) The requirements of paragraph (c)(1)(i) of this section, concerning the submission of 15-day Alert reports, shall also apply to any person (other than the applicant) whose name appears on the label of an approved drug product as a manufacturer, packer, or distributor. However, to avoid unnecessary duplication in the submission to FDA of, and followup to, reports required by paragraph (c)(1)(i) of this section, obligations of a nonapplicant may be met by submission of all reports of serious adverse drug experiences to the applicant. * * *

* * * * *

(f) *Reporting Form FDA–1639.* (1) Except as provided in paragraph (f)(3) of this section, the applicant shall complete a Form FDA–1639 (Adverse Reaction Report) for each report of an adverse drug experience.

* * * * *

(l) * * * For purposes of this provision, the term ''applicant'' also includes any person reporting under paragraph (c)(1)(ii) of this section.

* * * * *

## PART 600—BIOLOGICAL PRODUCTS: GENERAL

5. The authority citation for 21 CFR part 600 continues to read as follows:

**Authority:** Secs. 201, 501, 502, 503, 505, 510, 519, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374); secs. 215, 351, 352, 353, 361, 2125 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264, 300aa-25).

6. Section 600.80 is amended by removing the definition for *Increased frequency* in paragraph (a), by removing paragraph (c)(1)(ii), by redesignating paragraphs (c)(1)(iii) and (c)(1)(iv) as paragraphs (c)(1)(ii) and (c)(1)(iii), respectively, by revising the first sentence in the introductory text of newly redesignated paragraph (c)(1)(ii), by removing the last sentence in paragraph (d)(1), by revising paragraph (f)(1), and by revising the last sentence in paragraph (m) to read as follows:

**§ 600.80 Postmarketing reporting of adverse experiences.**

* * * * *

(c) * * *

(1) * * *

(ii) The requirements of paragraph (c)(1)(i) of this section, concerning the submission of 15-day Alert reports, shall also apply to any person other than the licensed manufacturer of the final product whose name appears on the label of a licensed biological product as a manufacturer, packer, distributor, shared manufacturer, joint manufacturer, or any other participant involved in divided manufacturing.

* * *

* * * * *

(f) *Reporting forms.* (1) Except as provided in paragraph (f)(3) of this section, the licensed manufacturer shall complete the reporting form designated by FDA (FDA–3500A, or, for vaccines, a VAERS form) for each report of an adverse experience.

* * * * *

(m) * * * For purposes of this provision, this paragraph also includes any person reporting under paragraph (c)(1)(ii) of this section.

Dated: June 19, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97–16684 Filed 6–20–97; 3:54 pm]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 520

### Oral Dosage Form New Animal Drugs; Gentamicin Sulfate Oral Solution

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for the use of gentamicin sulfate oral solution for the control and treatment of colibacillosis in weanling swine and for the control and treatment of swine dysentery caused by *Treponema hyodysenteriae*.

**EFFECTIVE DATE:** June 25, 1997.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

**SUPPLEMENTARY INFORMATION:** Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767, has filed ANADA 200–190, which provides for the control and treatment of colibacillosis in weanling swine caused by strains of *Escherichia coli* sensitive to gentamicin, and for the control and treatment of swine dysentery associated with *T. hyodysenteriae*.

ANADA 200–190 is approved as a generic copy of Schering-Plough Animal Health's Garasin® (gentamicin sulfate) oral solution in NADA 91–191. The ANADA is approved as of May 27, 1997, and the regulations are amended in 21 CFR 520.1044a(b) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**List of Subjects in 21 CFR Part 520**

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

## PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

**§ 520.1044a [Amended]**

2. Section 520.1044a *Gentamicin sulfate oral solution* is amended in paragraph (b) by removing ''No. 000061'' and adding in its place ''Nos. 000061 and 051259''.

Dated: June 12, 1997.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 97–16686 Filed 6–24–97; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF JUSTICE

## 28 CFR Part 16

**[AAG/A Order No. 137–97]**

## Exemption of Records Systems Under the Privacy Act

**AGENCY:** Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** The Department of Justice is exempting a Privacy Act system of records from subsections (c) (3) and (4); (d); (e) (1), (2), (3), (5) and (8); and (g) of the Privacy Act, 5 U.S.C. 552a. This system of records is maintained by the Immigration and Naturalization Service (INS) and is entitled ''Office of Internal Audit Investigations Index and Records, JUSTICE/INS–002.'' Information in this system relates to official Federal investigations and law enforcement matters of the Office of Internal Audit of the INS, pursuant to the Inspector General Act of 1978, 5 U.S.C. App., as amended by the Inspector General Act amendments of 1988. The exemptions are necessary to avoid interference with certain internal law enforcement functions of the INS for which records falling within the scope of subsections (j)(2) and (k)(2) may be generated. Specifically, the exemptions are necessary to prevent subjects of investigations from frustrating the investigatory process; to preclude the disclosure of investigative techniques; to protect the identities and physical safety of confidential informants and of law enforcement personnel; to ensure OIA's ability to obtain information from information sources; and to protect the privacy of third parties.

**EFFECTIVE DATE:** June 25, 1997.

**FOR FURTHER INFORMATION CONTACT:** Patricia E. Neely—202–616–0178.

**SUPPLEMENTARY INFORMATION:** On March 7, 1997 (62 FR 10495) a proposed rule was published in the **Federal Register** with an invitation to comment. No comments were received.

This order relates to individuals rather than small business entities. Nevertheless, pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601–612, it is hereby stated that the order will not have ''a significant economic impact on a substantial number of small entities.''

**List of Subjects in Part 16**

Administrative Practices and Procedures, Courts, Freedom of Information Act, Government in the Sunshine Act, Privacy Act.

Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order No. 793–78, 28 CFR part 16 is amended as set forth below.

Dated: June 6, 1997.

**Stephen R. Colgate,**

*Assistant Attorney General for Administration.*

1. The authority for Part 16 continues to read as follows:

**Authority:** 5 U.S.C. 301, 552, 552a, 552b(g), 553; 18 U.S.C. 4203(a)(1); 28 U.S.C. 509, 510, 534, 31 U.S.C. 3717, 9701.

2. 28 CFR 16.99 is amended by adding paragraphs (g) and (h) to read as follows:

**§ 16.99 Exemption of the Immigration and Naturalization Service Systems-limited access.**

* * * * *

(g) The Office of Internal Audit Investigations Index and Records (Justice/INS–002) system of records is exempt under the provisions of 5 U.S.C. 552a(j)(2) from subsections (c)(3) and (4); (d); (e)(1), (2), (3), (5) and (8); and (g), but only to the extent that this system contains records within the scope of subsection (j)(2), and to the extent that records in the system are subject to exemption therefrom. In addition, this system of records is also exempt under the provisions of 5 U.S.C. 552a(k)(2) from subsections (c)(3); (d); and (e)(1), but only to the extent that this system contains records within the scope of subsection (k)(2), and to the extent that records in the system are subject to exemption therefrom.

(h) The following justification apply to the exemptions from particular subsections:

(1) From subsection (c)(3) because the release of the disclosure accounting for disclosure could permit the subject of an actual or potential criminal or civil investigation to obtain valuable information concerning the existence and nature of the investigation, the fact that individuals are subjects of the investigation, and present a serious impediment to law enforcement.

(2) From subsection (c)(4) to the extent that the exemption from subsection (d) is applicable. Subsection (c)(4) will not be applicable to the extent that records in the system are properly withholdable under subsection (d).

(3) From the access and amendment provisions of subsection (d) because access to the records contained in this system of records could inform the subject of a criminal or civil investigation of the existence of that investigation; of the nature and scope of the information and evidence obtained as to their activities; of the identity of confidential sources, witnesses and law enforcement personnel; and of