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

information that may enable the subject to avoid detection or apprehension. Such disclosures would present a serious impediment to effective law enforcement where they prevent the successful completion of the investigation; endanger the physical safety of confidential sources, witnesses, and law enforcement personnel; and/or lead to the improper influencing of witnesses, the destruction of evidence, or the fabrication of testimony. In addition, granting access to these records could result in a disclosure that would constitute an unwarranted invasion of the privacy of third parties. Amendment of the records would interfere with ongoing investigations and law enforcement activities and impose an impossible administrative burden by requiring investigations to be continuously reinvestigated.

(4) From subsection (e)(1) because in the course of criminal or civil investigations, the Immigration and Naturalization Service often obtains information concerning the violation of laws other than those relating to violations over which INS has investigative jurisdiction, in the interests of effective law enforcement, it is necessary that INS retain this information since it can aid in establishing patterns of criminal activity and provide valuable leads for those law enforcement agencies that are charged with enforcing other segments of the criminal law.

(5) From subsection (e)(2) because in a criminal investigation, the requirement that information be collected to the greatest extent possible from the subject individual would present a serious impediment to law enforcement in that the subject of the investigation would be placed on notice of the existence of the investigation and would therefore be able to avoid detection or apprehension.

(6) From subsection (e)(3) because the requirement that individuals supplying information be provided with a form stating the requirements of subsection (e)(3) would constitute a serious impediment of criminal law enforcement in that it could compromise the existence of a confidential investigation, reveal the identify of confidential sources of information and endanger the life or physical safety of confidential informants.

(7) From subsection (e)(5) because in the collection of information for criminal law enforcement purposes it is impossible to determine in advance what information is accurate, relevant, timely, and complete. With the passage of time, seemingly irrelevant or untimely information may acquire new significance as further investigation brings new details to light and the accuracy of such information can only be determined in a court of law. The restrictions of subsection (e)(5) would restrict the ability of trained investigators and intelligence analysts to exercise their judgment in reporting on investigations and impede the development of criminal intelligence necessary for effective law enforcement.

(8) From subsection (e)(8) because the individual notice requirements of subsection (e)(8) could present a serious impediment to criminal law enforcement as this could interfere with the Immigration and Naturalization Service's ability to issue administrative subpoenas and could reveal investigative techniques and procedures.

(9) From subsection (g) for those portions of this system of records that were compiled for criminal law enforcement purposes and which are subject to exemption from the access provisions of subsections (d) pursuant to subsection (j)(2).

[FR Doc. 97–16595 Filed 6–24–97; 8:45 am]

BILLING CODE 4410–10–M

FEDERAL MEDIATION AND CONCILIATION SERVICE

29 CFR Part 1404

Arbitration Policy; Roster of Arbitrators, Procedures for Arbitration Services

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Final rule.

SUMMARY: This document revises Subparts A, B, and C of 29 CFR Part 1404. The goals of these revisions and additions are to more accurately reflect current practice, clarify the role of the Arbitrator Review Board, amend the standards for arbitrator listing on the Roster, streamline the primary arbitration process, and provide new services to our customers. The new rules also call for an annual listing fee for all arbitrators as well as a fee for all requests by the parties for names of arbitrators.

DATES: This regulation is effective October 1, 1997, except for § 1404.7 which will be effective September 1, 1997.

FOR FURTHER INFORMATION CONTACT: Peter Regner, 202–606/8181.

SUPPLEMENTARY INFORMATION: The Federal Mediation and Conciliation Service, in an effort to receive public input on ways to improve its arbitration services, published the draft revision of its proposed rules in the March 13, 1997, issue of the **Federal Register** (62 FR 11797) and conducted a formal all-day focus group on March 27, 1997. The focus group consisted of six (6) arbitrators, six (6) of the Service's top labor customers and six (6) of its leading management customers. In addition to the comments from the focus group, the Service received 68 written responses: 61 from arbitrators, six (6) from management, and one (1) from labor.

These regulations revise and supplement the rules under which the Office of Arbitration Services (OAS) has operated since April 15, 1979. Many of the changes simply describe operational changes which have evolved over the last 18 years but have never been formally documented. Other changes stem from a large-scale reinvention effort in which OAS employees, their union and management officials are attempting to operate in a more efficient and effective manner. Some revisions are aimed at improving the arbitration process by enforcing deadlines upon both the parties and the arbitrators.

In general, the public's response to the proposed rule changes was very favorable. Over one-fourth of the written responses indicated total support of all proposed changes. Only one proposed change failed to receive public support, and that issue has been removed from the final rule. Most comments supported the general policy and suggested minor revisions as to its implementation. More specific information about the public response is contained in the following section-by-section analysis.

Subpart A: Arbitration Policy; Administration of Roster

Sections 1404.1–1404.3

There were no changes made to the Proposed Rule.

Subpart B: Roster of Arbitrators; Admission and Retention

Section 1404.4–1404.7

Section 1404.5

Subsection (b). The proposed rule has been changed by stating that qualifications for recommending listing on the Roster ''may'' rather than ''shall'' be demonstrated by submission of five (5) rather than ''at least five (5)'' awards. The rule also was changed by stating ''The [Arbitrator Review] Board will consider experience'' instead of ''may consider experience'' in lieu of such awards. These changes reflect several