effect of suspension or termination of contributions, effect of merger or termination of the plan, the provisions governing administration of the plan, a description of the management and investment of plan funds, and other provisions relating to the rights or obligations of participants or beneficiaries.

It is proposed also, that administrators of pension plans who have previously filed a plan description will be required to file a new plan description, or file an amendment to the plan description previously filed, in order that the information referred to herein will be available to participants and beneficiaries of such plans.

Additionally, it is proposed to require administrators of pension benefit plans to notify participants that copies of the description of the plan, and the latest annual report required by section 7 of the Act, are available for examination by any participant or beneficiary at the principal office of the plan, and that a copy of the plan description and an adequate summary of the latest annual report will be mailed to a participant or beneficiary on written request. Whenever such plan is amended it is also proposed that administrators must notify participants as to the subject of the amendment(s), that the amendment(s) will be available in the principal office, and will be mailed on written request.

Interested persons are invited to submit written data, views, or comments regarding the proposed rule to the Assistant Secretary of Labor for Labor-Management Relations, U.S. Department of Labor, Washington, D.C. 20210, within 30 days of publication of this notice in the FEDERAL REGISTER.

Copies of the amendatory material to the Form D–1 may be obtained by writing to the Office of Public Information, U.S. Department of Labor, Washington, D.C. 20210. All written materials or suggestions submitted in response to this notice of proposed rule making will be available for public inspection in Room 401, American National Bank Building, 8701 Georgia Avenue, Silver Spring, MD, during regular business hours.

Accordingly, it is proposed herewith to amend 29 CFR Part 460 as follows:

1. The Authority for issuing Part 460 is amended to read as follows:

AUTHORITY: The provisions of this Part 460 issued under sections 5, 6, 7, 8, 72 Stat. 999, 1000, 1002, 76 Stat. 36, 37; 29 U.S.C. 304, 305, 306, 307; Secretary's Order 16–68 (33 F.R. 15574).

2. A new § 460.1a is hereby added to 29 CFR Part 460 to read as follows:

§ 460.1a Notification of availability of plan descriptions and annual reports.

The administrator of any employee pension benefit plan subject to the Welfare and Pension Plans Disclosure Act shall notify the participants of such plan in writing that pursuant to the provisions of section 8 of the Act, participants or beneficiaries are entitled to examine copies of the description of the plan and the latest annual report at the principal office of the plan. Such notice shall identify the location of such office, and the hours during which such reports will be available for examination, and indicate that a copy of the description of the plan and an adequate summary of the annual report will be delivered to a plan participant or beneficiary upon receipt of a written request therefor by the administrator of the plan. Whenever such plan is amended the plan administrator shall cause participants to be notified in writing as to the subject of the amendment(s), and that a copy of the amendments(s) will be made available for examination at the principal office of the plan, or upon written request delivered to a participant or beneficiary.

3. Section 460.2 is amended by designating the existing section as paragraph (a) and adding a paragraph (b) to read as follows:

§ 460.2 Content of reports—signature or certification.

* * * * *

(b) In addition the administrator of each pension benefit plan shall, as part of the Form D–1[1] and in accordance with the instructions contained in the form, file a comprehensive description of the provisions of the plan relating to the eligibility requirements to participate under the plan; vesting provisions, including conditions under which vested benefits may be divested; sources of contributions, amount, periods when due, whether by check off or direct payment; benefits provided under the plan and the method by which they are computed; procedures to be followed in presenting claims for benefits and for appealing denial of claims; the effect of suspension or termination of contributions; the effect of merger or termination of the plan; details as to the administration of the plan; a description of the management and investment of plan funds; and other provisions which relate to the rights or obligations of participants or beneficiaries under the plan. Such information shall be written in a manner calculated to be understood by the average participant or beneficiary. If plan booklets are distributed to participants or beneficiaries such booklets should include the information provided for in this paragraph.

4. Section 460.5 is hereby amended by changing the heading of the section and by adding a new paragraph (c) as follows:

§ 460.5 Filing plan description amendments.

* * * * *

(c) Administrators of pension plans who have previously submitted a plan description pursuant to § 460.2 but which does not include a description of the plan as provided for in paragraph (b) of § 460.2 shall submit a revised description of the plan containing information provided for in paragraph (b) of § 460.2 on revised Form D–1 incorporating all current information required therein, or shall submit an addendum to the Form D–1 originally filed, containing the information required under paragraph (b) of § 460.2 and questions 13 and 14 of the Form D–1 as revised. Such new description or such addendum shall be submited to the Office of Labor-Management and Welfare-Pension Reports, U.S. Department of Labor, Washington, D.C. 20210, within 120 days after the effective date of this paragraph.

Signed at Washington, D.C., this 27th day of January 1972.

W. J. USERY, Jr.,
Assistant Secretary of Labor for Labor-Management Relations.

[FR Doc.72–1415 Filed 1–31–72;8:46 am]

[1] Filed as part of the original document.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 135]

ANTIBIOTIC AND SULFONAMIDE DRUGS IN ANIMAL FEEDS

Proposed Statement of Policy

In April, 1970 the Commissioner of Food and Drugs established a Task Force of scientists to undertake a comprehensive review of the use of antibiotic drugs in animal feeds. The scientists included ten specialists on infectious diseases and animal science from the Food and Drug Administration (FDA), the National Institutes of Health, the U.S. Department of Agriculture, and the Center for Disease Control and five representatives from universities and industry.

The Task Force was established on the recommendation of the FDA Science Advisory Committee following its review of a report issued by the Government of Great Britain on the use of antibiotics in veterinary medicine and animal husbandry. The British study, known as the Swann Committee Report, recommended that antibiotics should be divided into "feed" antibiotics and "therapeutic" antibiotics and that only those antibiotics not used for treatment of diseases in man should be allowed in animal feeds at the so-called growth promotion level.

The Food and Drug Administration has been studying the effects of low-level feeding of antibiotics to animals for a number of years, has held symposia, and has consulted with outside experts to review the nonmedical uses of antibiotics in animal feeds. The results of these studies and other documentation formed the background for the Task Force deliberations.

The Task Force concluded that the current conditions relating to its study are:

1. The use of antibiotic and sulfonamide drugs, especially in growth promotant and subtherapeutic amounts, favors the selection and development of single and multiple antibiotic resistant and R-factor bearing bacteria.

2. Animals which have received either subtherapeutic and /or therapeutic amounts of antibiotic and sulfonamide drugs in feeds may serve as a reservoir of antibiotic resistant pathogens and nonpathogens. These reservoirs of pathogens can produce human infections.

3. The prevalence of multiresistant R-factor bearing pathogenic and nonpathogenic bacteria in animals has increased and has been related to the use of antibiotics and sulfonamide drugs.

4. Organisms resistant to antibacterial agents have been found on meat and meat products.

5. There has been an increase in the prevalence of antibiotic and sulfonamide resistant bacteria in man.

The Task Force identified three primary areas of concern, human health hazard, animal health hazard, and antibiotic effectiveness. Guidelines for establishing criteria were developed which must be considered with regard to the addition of growth promotant or subtherapeutic levels of antibacterial agents to animal feeds.

Based upon extensive documentation the Task Force concluded that:

1. Human illnesses and death have been reported due to both antibiotic-sensitive and antibiotic-resistant bacteria of animal origin. Food-producing animals constitute a major reservoir of certain bacteria (e.g., Salmonella) pathogenic for man. Evidence suggests that the use of certain antibiotics in food-producing animals promotes an increase in the animal reservoir of Salmonella through promotion of cross-colonization and infection, prolongation of the carrier state, and relapse of disease. Furthermore, the use of some antibiotics in animals produces a marked increase in the prevalence of R-factor containing bacteria which may be transmissible to man's enteric flora. These observations lead to the logical conclusion, though not fully documented, that such practices give rise to a human health hazard.

2. The continuous feeding of certain antibiotics to animals has been reported to compromise the treatment of certain animal diseases. Additional information is needed to quantitate the extent of this problem. Epidemiological and controlled challenge studies are needed to determine the relationship of the use of antibiotics in animal feeds and the subsequent treatment of diseases in animals which have been fed antibiotics.

3. The categorization of antibiotics into those for human and those for animal use should be based on scientific evaluations of the efficacy of each use and the impact that the use will have on all aspects of the public health. Such categorization must not result in compromising the availability of effective antimicrobials for humans or animals. However, it is the consensus of the Task Force that it would be highly desirable that in the future, a group of antibacterial agents be reserved exclusively for human use.

4. Limiting the types of antibiotics permitted in animal feeds is a step toward controlling the numbers of microorganisms resistant to antibiotics. Research is needed to investigate methods for improving weight gain and feed efficiency with drug agents and animal husbandry practices which do not cause the development of organisms resistant to antimicrobials.

5. When drug withdrawal times are not adhered to, antibiotic residues may be present in meat and meat products.

The Task Force therefore recommended that the following restrictions be placed into effect regarding the use of antibacterial agents in animal feeds at growth promotion and subtherapeutic levels:

1. Antimicrobial agents used in human clinical medicine that fail to meet the criteria based upon the guidelines referred to above be prohibited from use in animal feeds by the following dates: Tetracyclines, streptomycin, dihydrostreptomycin, sulfonamides and penicillins in poultry by January 1, 1973, and in swine, cattle, and sheep by July 1, 1973; all other antimicrobial agents used in human clinical medicine and approved for use in animal feeds by December 31, 1973.

2. Following the dates indicated, tetracycline, streptomycin, dihydrostreptomycin, neomycin, spectinomycin, penicillins, and the sulfonamides shall be reserved for therapy unless they meet the criteria established on the basis of the Task Force's guidelines in regard to the safety and efficacy for growth promotion or any subtherapeutic use; and furthermore, these antimicrobials, when used at therapeutic levels and for short-term treatments be administered only by or on the order of a licensed veterinarian.

3. That antibiotics which select for bacteria resistant to the antibiotics most critically needed for therapy of man and animals be prohibited from use in animal feeds. In this category at the present time are: chloramphenicol, semisynthetic penicillins, gentamicin, and kanamycin. Other antibiotics which have proven to be effective and essential for the therapy of certain animal diseases and which select for R-factor medicated multiple resistance be available for short-term use at therapeutic levels but only by a veterinarian or on his prescription.

4. That labeling for medicated feeds be required to state the amount of antibiotic in the final feed for all levels including growth levels.

Therefore, pursuant to the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-51; 21 U.S.C. 360b, 371(a)) and under the authority delegated to the Commissioner (21 CFR 2.120), it is proposed that Part 135 be amended by adding thereto the following new section:

§ 135.109 Antibiotic and sulfonamide drugs in animal feeds.

(a) The Commissioner will propose to revoke currently permitted uses of subtherapeutic and/or growth promotant uses of antibacterial agents in feeds, whether granted by approval of new animal drug applications, master files and/or antibiotic or food additive regulations, when such drugs are also used in human clinical medicine, unless data are submitted which establish their safety and effectiveness under specific criteria based on the guidelines contained in the Report of the FDA Task Force on the Use of Antibiotics in Animal Feeds.

(b) Within 30 days following the effective date of this regulation any person interested in retaining approval of tetracyclines, streptomycin, dihydrostreptomycin, sulfonamides, and penicillins for use in poultry after January 1, 1973, or in swine, cattle, and sheep after July 1, 1973, or of all other such approved antibiotics after December 31, 1973, shall satisfy the Commissioner in writing that studies adequate and appropriate to meet the prescribed criteria have been undertaken. Progress reports shall be filed on such studies every January 1 and July 1 until completion.

(c) Following implementation of the requirements of paragraphs (a) and (b) of this section:

(1) Those antibacterial drugs which fail to meet the prescribed criteria will be reserved for high-level, short-term use and shall be used only by or on the order of a licensed veterinarian.

(2) Animal feeds containing antibacterial drugs permitted to remain in use for growth promotion and/or subtherapeutic purposes shall be labeled to include a statement of the quantity of such drugs in finished feeds.

Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: January 25, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.72-1416 Filed 1-31-72;8:46 am]

Social and Rehabilitation Service

[45 CFR Parts 220, 222]

SERVICE PROGRAMS FOR FAMILIES AND CHILDREN AND FOR AGED, BLIND, OR DISABLED PERSONS

Notice of Proposed Rule Making

Notice is hereby given that the regulations set forth in tentative form below are proposed by the Administrator, Social and Rehabilitation Service, with the approval of the Secretary of Health, Education, and Welfare. The proposed regulations define organizational separation of services from assistance payments and require States to develop plans for and to implement such separation.

Prior to the adoption of the proposed regulations, consideration will be given to any comments, suggestions, or objections thereto which are submitted in writing