

NOTICES

in the FEDERAL REGISTER of April 12, 1969 (34 F.R. 6447), to be a new animal drug for which an approved new animal drug application is not in effect. Any such drug then on the market would be subject to regulatory proceedings.

Within 30 days after publication hereof in the FEDERAL REGISTER, such persons are required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Office of the General Counsel, Room 6-62, 5600 Fishers Lane, Rockville, Md. 20852, a written appearance electing whether:

1. To avail themselves of the opportunity for a hearing; or
2. Not to avail themselves of the opportunity for a hearing.

If such persons elect not to avail themselves of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing the approval of the new animal drug application.

Failure of such persons to file a written appearance of election within said 30 days will be construed as an election by such persons not to avail themselves of the opportunity for a hearing.

The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in his appearance.

If such persons elect to avail themselves of the opportunity for a hearing, they must file a written appearance requesting the hearing and giving the reasons why approval of the new animal drug application should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data they are prepared to prove in support of their opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing. When it clearly appears from the data in the application and from the reasons and factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the withdrawal of approval of the application, the Commissioner will enter an order on these data, making findings and conclusions on such data. If a hearing is requested and justified by the response to this notice, the issues will be defined, a hearing examiner will be named, and he shall issue a written notice of the time and place at which the hearing will commence, not more than 90 days after the expiration of such 30 days unless the hearing examiner and the applicant otherwise agree.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-51; 21 U.S.C. 360b) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: September 23, 1970.

SAM D. FINE,
Associate Commissioner
for Compliance.

[F.R. Doc. 70-13188; Filed, Oct. 1, 1970;
8:46 a.m.]

[Docket No. FDC-D-180; NADA No. 8-695V]

NORDEN LABORATORIES, INC.

Fomene; Notice of Withdrawal of Approval of New Animal Drug Application

A notice of opportunity for a hearing on the matter of withdrawing approval of new animal drug application No. 8-695V for Fomene was published in the FEDERAL REGISTER of July 17, 1970 (35 F.R. 11535). Norden Laboratories, Inc., 601 West Oak, Lincoln, Nebr. 68501, holder of said application, filed a letter requesting a hearing, but did not file adequate data to support such a request. The Commissioner of Food and Drugs concludes that there is no genuine and substantial issue of fact to justify a hearing (35 F.R. 7250; May 8, 1970).

Based on the foregoing finding and on the grounds set forth in the said notice of opportunity for hearing, the Commissioner concludes that approval of new animal drug application No. 8-695V should be withdrawn. Therefore, pursuant to the provision of the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-47; 21 U.S.C. 360b(e)) and under authority delegated to the Commissioner (21 CFR 2.120), approval of new animal drug application No. 8-695V, including all amendments and supplements thereto, is hereby withdrawn effective on the date of signature of this document.

Dated: September 18, 1970.

SAM D. FINE,
Associate Commissioner
for Compliance.

[F.R. Doc. 70-13189; Filed, Oct. 1, 1970;
8:48 a.m.]

[DESI 0061 NV]

BACITRACIN WITH OR WITHOUT PENICILLIN

Drugs for Veterinary Use; Drug Efficacy Study Implementation

There was an announcement published in the FEDERAL REGISTER of July 17, 1970 (35 F.R. 11531), regarding the efficacy of certain products which contain bacitracin with or without penicillin. Based on reevaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, the Commissioner of Food and Drugs concludes that the first sentence in the first paragraph following the list of products in said announcement should be amended to read as follows: "The Academy evaluated these products as probably effective for the growth claim in poultry, probably not effective for the

therapeutic claims, and the Academy stated that more information is needed for the growth claim in swine."

This notice is issued pursuant to provisions of the Food, Drug, and Cosmetic Act (secs. 502, 512, 52 Stat. 1050-51, as amended, 82 Stat. 343-51; 21 U.S.C. 352, 360b) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: September 18, 1970.

SAM D. FINE,
Associate Commissioner
for Compliance.

[F.R. Doc. 70-13190; Filed, Oct. 1, 1970;
8:46 a.m.]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

ASSISTANT SECRETARY FOR METROPOLITAN PLANNING AND DEVELOPMENT

Delegation of Authority

The delegation of authority to the Assistant Secretary for Metropolitan Planning and Development, effective February 7, 1970 (35 F.R. 2745), is amended as follows:

I. Revise section D to read:

SEC. D. *Authority to redelegate.* The Assistant Secretary for Metropolitan Planning and Development is authorized to redelegate to employees of the Department any of the authority delegated under section A.

II. Add the following section E immediately following section D:

SEC. E. *Exercise of redelegated authority.* Redelegations of final authority pursuant to section D of this delegation shall not be construed to modify or otherwise affect the administrative and supervisory powers of the Regional Administrator and Area Director, and their respective deputies, to whom a delegate is responsible, and these supervisors shall, in addition to any other authority delegated to them, have the same final authority redelegated to their subordinates.

III. Change existing section E to read "Section F."

(Sec. 7(d), Department of HUD Act, 42 U.S.C. 3535(d))

Effective date. This amendment of delegation of authority shall be effective as of September 1, 1970.

GEORGE ROMNEY,
Secretary of Housing and
Urban Development.

[F.R. Doc. 70-13215; Filed, Oct. 1, 1970;
8:48 a.m.]

REGIONAL ADMINISTRATORS ET AL.

Redelegation of Authority With Respect to Metropolitan Planning and Development Programs

SECTION A. *Authority redelegated with respect to specific programs.* I. Each Regional Administrator, Deputy Regional