

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Roussel-UCLAF, Division Agro-Veterinaire. The supplemental NADA provides for use of an ear implant containing trenbolone acetate and estradiol in pasture heifers (in addition to a previously approved use in pasture steers) for increased rate of weight gain.

EFFECTIVE DATE: August 9, 1996.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0217.

SUPPLEMENTARY INFORMATION: Roussel-UCLAF, Division Agro-Veterinaire, 163 Avenue Gambetta, 75020 Paris, France, filed supplemental NADA 140-897, which provides for use of Revalor®-G, an ear implant, each dose containing 2 pellets, each pellet containing 20 milligrams (mg) of trenbolone acetate and 4 mg of estradiol. The implant is used in pasture heifers (slaughter, stocker, and feeder) (pasture steers being already approved) for increased rate of weight gain. The supplemental NADA is approved as of July 2, 1996, and the regulations are amended in 21 CFR 522.2477(c)(3) 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for a 3-year period of marketing exclusivity beginning on July 2, 1996, because new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval were conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no

significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

2. Section 522.2477 is amended by revising the heading of paragraph (c)(3) and paragraph (c)(3)(iii) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(c) * * *

(3) *Pasture cattle (slaughter, stocker, feeder steers, and heifers).*

* * * * *

(iii) *Limitations.* Implant subcutaneously in ear only. Not for use in animals intended for subsequent breeding or in dairy animals.

Dated: July 19, 1996.

Robert C. Livingston,
Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.
[FR Doc. 96-20344 Filed 8-8-96; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF STATE

Bureau of Political-Military Affairs

22 CFR Part 126

[Public Notice 2407]

Amendment to the List of Proscribed Destinations

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to reflect that it is no longer the policy of the United States to deny licenses, other approvals, exports and imports of defense articles and defense services, destined for or

originating in Georgia, Kazakstan, Kyrgyzstan, Moldova, Turkmenistan and Uzbekistan. All requests for approval involving items covered by the U.S. Munitions List will be reviewed on a case-by-case basis.

EFFECTIVE DATE: July 17, 1996.

FOR FURTHER INFORMATION CONTACT:

Gordon J. Stirling, Office of Arms Transfer and Export Control Policy, Bureau of Political-Military Affairs, Department of State (202/647-0397).

SUPPLEMENTARY INFORMATION: In connection with the President's policy that U.S. laws and regulations be updated to reflect the end of the Cold War, the Department of State is amending the ITAR to reflect that it is no longer the policy of the United States, pursuant to § 126.1, to deny licenses, other approvals, exports and imports of defense articles and defense services, destined for or originating in Georgia, Kazakstan, Kyrgyzstan, Moldova, Turkmenistan and Uzbekistan. Requests for licenses or other approvals for these states involving items covered by the U.S. Munitions List (22 CFR part 121) will no longer be presumed to be disapproved.

This amendment to the ITAR involves a foreign affairs function of the United States and thus is excluded from the major rule procedures of Executive Order 12291 (46 FR 13193) and the procedures of 5 U.S.C. 553 and 554. This final rule does not contain a new or amended information requirement subject to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

List of Subjects in 22 CFR Part 126

Arms and Munitions, Exports.

Accordingly, under the authority of Section 38 of the Arms Export Control Act (22 U.S.C. 2778) and Executive Order 11958, as amended, 22 CFR Subchapter M is amended as follows:

PART 126—[AMENDED]

1. The authority citation for part 126 continues to read as follows:

Authority: Secs. 2, 38, 40, 42, and 71, Arms Export Control Act, Pub. L. 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2780, 2791, and 2797); E.O. 11958, 41 FR 4311; E.O. 11322, 32 FR 119; 22 U.S.C. 2658; 22 U.S.C. 287c; E.O. 12918, 59 FR 28206.

§ 126.1 [Amended]

2. Section 126.1 is amended by removing "Georgia," "Kazakhstan," "Kyrgyzstan," "Moldova," "Turkmenistan," and "Uzbekistan" from paragraph (a).

Dated: July 11, 1996.

Lynn E. Davis,

*Under Secretary of State for Arms Control
and International Security Affairs.*

[FR Doc. 96-20373 Filed 8-8-96; 8:45 am]

BILLING CODE 4710-25-M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 252 and 290

[Notice No. 835; Re: Notice Numbers 752,
754, 761 and 764]

RIN 1512-AA98 and 1512-AB03

Exportation of Alcoholic Beverages, Denatured Alcohol, Tobacco Products and Cigarette Papers and Tubes (95R- 046P)

AGENCY: Bureau of Alcohol, Tobacco
and Firearms (ATF), Department of the
Treasury.

ACTION: Advance notice of proposed
rulemaking.

SUMMARY: As part of a regulatory reform
initiative, the Bureau of Alcohol,
Tobacco and Firearms (ATF) is
proposing to revise and recodify the
regulations covering exportation of
alcoholic beverages, beer concentrate,
specially denatured alcohol, tobacco
products, and cigarette papers and
tubes. Proposed changes include: setting
standards for satisfactory evidence of
exportation, streamlining export
procedures, and reducing the paperwork
burden on exporters.

DATES: Written comments must be
received by October 8, 1996.

ADDRESSES: Send written comments to:
Chief, Wine, Beer and Spirits
Regulations Branch, Bureau of Alcohol,
Tobacco and Firearms, P.O. Box 50221,
Washington, DC 20091-0221, *Attn:*
Notice No. 835. Copies of written
comments received in response to this
advance notice of proposed rulemaking
will be available for public inspection
during normal business hours at: ATF
Reference Library, Office of Public
Affairs and Disclosure, Room 6300, 650
Massachusetts Avenue, NW.,
Washington, DC 20226.

FOR FURTHER INFORMATION CONTACT:
Marjorie D. Ruhf, Wine, Beer and Spirits
Regulations Branch, Bureau of Alcohol,
Tobacco and Firearms, 650
Massachusetts Avenue, NW.,
Washington, DC 20226 (202-927-8230).

SUPPLEMENTARY INFORMATION:

Background

On February 21, 1995, President
Clinton announced a regulatory reform
initiative. As part of this initiative, each
Federal agency was instructed to
conduct a page by page review of all
agency regulations to identify those
which are obsolete or burdensome and
those whose goals could be better
achieved through the private sector,
self-regulation or state and local
governments. In cases where the
agency's review disclosed regulations
which should be revised or eliminated,
the agency would propose
administrative changes to its
regulations. In addition, on April 13,
1995, the Bureau published Notice 809
(60 FR 18783) requesting comments
from the public regarding which ATF
regulations could be improved or
eliminated. No specific comments were
received from the public concerning 27
CFR parts 252 and 290, but the Bureau
wishes to substantially revise these
parts of the regulations for reasons
discussed later in the supplementary
information.

Statutory Basis for Regulations

Since ATF wishes to open all areas of
the export regulations for comment at
this time, we will begin with a brief
summary of the underlying statutes. In
particular, we note there are some areas
where the statutory treatment of
different commodities varies widely.
Any future regulations will reflect these
statutory differences.

Distilled spirits may be withdrawn
without payment of tax for exportation
(after making such application, filing
such bonds, and complying with such
other requirements as may be
regulations be prescribed), for transfer to
foreign-trade zones, for use of certain
vessels and aircraft, or for transfer to a
customs bonded warehouse for
exportation, storage pending
exportation, or withdrawal and use by
eligible diplomatic personnel. See 26
U.S.C. 5175, 5214 and 5066.

Wine may be withdrawn from bonded
premises without payment of tax for
export by the proprietor or by any
authorized exporter (under such
regulations and bonds as the Secretary
may deem necessary); for transfer to any
foreign-trade zone; for use of certain
vessels and aircraft as authorized by
law; or for transfer to any customs
bonded warehouse. Wine entered into
customs bonded warehouses may be
withdrawn free of tax by eligible
diplomatic personnel. See 26 U.S.C.
5362.

Beer may be removed from brewery
premises without payment of tax for
exportation, use as supplies for certain
vessels and aircraft, or deposit in a
foreign trade zone for exportation or
storage pending exportation (in such
containers and under such regulations,
and on the giving of such notices,
entries, and bonds and other security, as
the Secretary may by regulations
prescribe). The brewer may also
withdraw beer concentrate without
payment of tax for exportation or for
deposit in a foreign trade zone. See 19
U.S.C. 81c, 26 U.S.C. 5053.

Distilled spirits may be withdrawn
free of tax for exportation after
denaturation in the manner prescribed
by law. See 26 U.S.C. 5214.

When taxpaid distilled spirits which
have been manufactured, produced,
bottled, or packaged in the United States
and marked especially for export are
exported, laden for use as supplies on
qualified vessels or aircraft, deposited in
a foreign trade zone for exportation or
storage pending exportation, or
deposited in a customs bonded
warehouse for tax free withdrawal and
use by accredited foreign diplomatic
personnel, the bottler or packager of the
spirits may claim drawback of the taxes
paid. The Secretary is authorized to
prescribe regulations governing the
determination and payment or crediting
of drawback, including the requirements
of such notices, bonds, bills of lading,
and other evidence indicating payment
and determination of tax and
exportation as are deemed necessary.
See 19 U.S.C. 81c and 1309, 26 U.S.C.
5062, 5066.

When taxpaid wine which has been
manufactured, produced, bottled, or
packaged in the United States is
exported, laden for use as supplies on
qualified vessels or aircraft, or deposited
in a foreign trade zone for exportation
or storage pending exportation,
drawback of tax may be claimed by the
proprietor of the bonded wine cellar,
taxpaid wine bottling house, or
wholesale liquor dealer who withdrew
the wine. The Secretary is authorized to
prescribe regulations governing the
determination and payment or crediting
of drawback, including the requirements
of such notices, bonds, bills of lading,
and other evidence indicating payment
and determination of tax and
exportation as are deemed necessary.
See 19 U.S.C. 81c and 1309, 26 U.S.C.
5062, 5066.

On the exportation of beer which has
been brewed or produced in the United
States, the brewer thereof shall be
allowed a drawback equal in amount to
the tax found to have been paid on such
beer, to be paid on submission of such