**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

21 CFR Part 522

**Implantation or Injectable Dosage Form New Animal Drugs; Furosemide**

**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 Phoenix Scientific, Inc. The ANADA provides for use of furosemide solution by intramuscular or intravenous injection in horses, cattle, dogs, and cats.

**DATES:** This rule is effective April 15, 2002.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine, 2100 W. Executive Blvd., Suite 5650, Silver Spring, MD 20991. Telephone: 240–208–6001. E-mail: lluther@cvn.fda.gov.

**SUPPLEMENTARY INFORMATION:**

In accordance with the Freedom of Information Act (5 U.S.C. 552(a)) as amended by the Information Technology Improvement Act of 1996 (P.L. 104–106), the agency has determined that the Freedom of Information Act reports which are not ATF forms, other reports, which are not ATF forms, with whom applications, notices, and other reports, which are not ATF forms, are filed.

**EFFECTIVE DATE:** This rule is effective April 15, 2002.

**FOR FURTHER INFORMATION CONTACT:** Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW., Room 5003, Washington, DC 20226 (telephone 202–927–8210 or e-mail to aclotob@atfhq.atf.treas.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

Pursuant to Treasury Order 120–01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of chapter 51 of the Internal Revenue Code of 1986 (IRC) and the Federal Alcohol Administration (FAA) Act. The Director has subsequently delegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain which particular officer is authorized to perform a particular function under chapter 51 of the IRC or the FAA Act, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, this final rule rescinds all authorities of the Director in part 252 that were previously delegated and places those authorities with the “appropriate ATF officer.” Most of the authorities of the Director that were not previously delegated are also placed with the “appropriate ATF officer.” Along with this final rule, ATF is publishing ATF Order 1130.27 Delegation of the Director’s Authorities for Tobacco and Firearms (ATF).
in 27 CFR part 252, Exportation of Liquors, which delegates certain of these authorities to the appropriate organizational level. The effect of these changes is to consolidate all delegations of authority in part 252 into one delegation instrument. This action both simplifies the process for determining which ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the future. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

In addition, this final rule also eliminates all references in the regulations that identify the specific ATF officer with whom an ATF form is filed. This action is taken because ATF forms will indicate the officer with whom they must be filed. Similarly, this final rule also amends part 252 to provide that the submission of documents other than ATF forms (such as letterhead applications, notices and reports) must be filed with the “appropriate ATF officer” identified in ATF Order 1130.27. These changes will help identify the officer with whom forms and other required submissions are filed.

This final rule also makes various technical amendments to Subpart A—Scope of 27 CFR Part 252. First, a new § 252.4 is added to recognize the authority of the Director to delegate regulatory authorities in part 252 and to identify ATF Order 1130.27 as the instrument reflecting such delegations. Second, § 252.2 is amended to provide that the instructions for an ATF form identify the ATF officer with whom it must be filed.

ATF has made or will make similar changes in delegations to all other parts of Title 27 of the Code of Federal Regulations through separate rulemakings.

Corrections and Miscellaneous Changes

In the definition of “district director of customs” in 27 CFR 252.11 we have removed the repetition of the word “district.”

In four sections of part 252, we are correcting references of “part 240” to “part 24.”

Throughout 27 CFR part 252, we are revising ATF form numbers to reflect the correct numbers as shown on the following table:

<table>
<thead>
<tr>
<th>Form No.</th>
<th>Revised form No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>700</td>
<td>5120.36</td>
</tr>
<tr>
<td>1582-A</td>
<td>1582-A (5120.24)</td>
</tr>
<tr>
<td>1582-B</td>
<td>1582-B (5130.6)</td>
</tr>
<tr>
<td>1689</td>
<td>1689 (5130.12)</td>
</tr>
<tr>
<td>2177</td>
<td>2177 (510.58)</td>
</tr>
<tr>
<td>2605</td>
<td>2605 (5120.20)</td>
</tr>
</tbody>
</table>

We are removing § 252.195a since any claims filed for drawback on spirits tax determined before January 1, 1980, should have been filed.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) do not apply. A copy of this final rule was submitted to the Chief Counsel for Advocacy of the Small Business Administration in accordance with 26 U.S.C. 7805(f). No comments were received.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action because it will not: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866.

Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming changes to improve the clarity of the regulations, it is unnecessary to issue this final rule with notice and public procedure under 5 U.S.C. 553(b).

Similarly it is unnecessary to subject this final rule to the effective date limitation of 5 U.S.C. 553(d).

Drafting Information

The principal author of this document is Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 252

Administrative practice and procedure, Aircraft, Alcohol and alcoholic beverages, Armed forces, Authority delegations (Government agencies), Beer, Claims, Excise taxes, Exports, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Surety bonds, Transportation, Vessels, Warehouses, Wine.

Authority and Issuance

Title 27, Code of Federal Regulations is amended as follows:

PART 252—EXPORTATION OF LIQUORS

§§ 252.2 and 252.20 [Amended]

Par. 2. Remove the word “Director” each place it appears and add, in substitution, the words “appropriate ATF officer” in the following places: (a) Section 252.2(a); and (b) Section 252.20(a)(2) introductory text, (a)(3) and (a)(4).

Par. 3. Amend § 252.2 by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 252.2 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 4. In Subpart A—Scope, a new § 252.4 is added as follows:

§ 252.4 Delegations of the Director.

Most of the regulatory authorities of the Director contained in this part 252 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.27, Delegation of the Director’s Authorities in this part 252, Exportation of Liquors. ATF delegation orders, such as ATF Order 1130.27, are available to any
§ 252.11 Meaning of Terms.

* * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.27, Delegation to perform any functions relating to the Tobacco and Firearms (ATF) authorized by the Director (compliance) and removing the definition of “Bonded wine cellar” and adding in its place a definition of “District director of customs” to read as follows:

§ 252.20 Alternate methods or procedures—

(a) Alternate methods or procedures—

(1) Application. An exporter, after receiving approval from the appropriate ATF officer, may use an alternate method or procedure (including alternate construction or equipment) in lieu of a method or procedure prescribed by this part. An exporter wishing to use an alternate method or procedure may apply to the appropriate ATF officer.

* * * *

(c) Withdrawal of approval. If the appropriate ATF officer finds the revenue is jeopardized or the effective administration of this part is hindered by the approval, such ATF officer may withdraw approval for an alternate method or procedure or for an emergency variation from requirements, approved under paragraph (a) or (b) of this section.


Par. 7. Remove the words “regional director (compliance)”, “regional director’s (compliance)”, or “regional directors (compliance)” and add, in substitution, the words “appropriate ATF officer”, “appropriate ATF officer” or “appropriate ATF officers”, respectively, each place it occurs in the following places:

a. Section 252.20(b)(1), (b)(2) introductory text and (b)(3); b. The last two sentences of § 252.22; c. The undesignated paragraph of § 252.36; d. Section 252.37; e. Section 252.38; f. Section 252.43(a)(6) and (b)(3); g. Section 252.52a; h. Section 252.55; i. The introductory text of § 252.56; j. The last sentence of § 252.58(c); k. Section 252.62(b); l. Section 252.67; m. Section 252.70; n. Section 252.71; o. The second and third sentences of § 252.72; p. Section 252.74; q. Section 252.96; r. Section 252.103(b); s. The last sentence of § 252.117; t. Section 252.122(c) and (d); u. Section 252.123(b); v. Section 252.125; w. The last sentence of § 252.131; x. Section 252.146; y. The last sentence of § 252.147; z. The last sentence of § 252.162; aa. The last sentence of § 252.171; bb. Paragraphs (b) and (c) of § 252.195b; cc. The last sentence of § 252.211; dd. Section 252.218; ee. The last sentence of § 252.221; ff. Section 252.226; gg. The second sentence of § 252.265; hh. Section 252.266; ii. Section 252.269(c); jj. Section 252.275; kk. Section 252.282; ll. The third sentence of § 252.285; mm. The last sentence of the introductory text of § 252.290; nn. Section 252.301; oo. Section 252.302; pp. The last sentence of § 252.303; qq. Section 252.304; rr. Section 252.310; ss. Section 252.315; tt. Section 252.316; uu. The last sentence of § 252.317; vv. Section 252.320; ww. Section 252.321; xx. Section 252.331; yy. Section 252.332; zz. Section 252.333 and aaaa. Section 252.335.


Par. 8. Add the numbers and parentheses “(5120.24)” after the characters “1582–A” each place they occur in the following places:

a. Section 252.22; b. Section 252.36(c); c. Section 252.65; d. Section 252.214; e. Section 252.215; f. Section 252.218; g. Section 252.220(b); h. Section 252.220a; i. Section 252.250(a)(4); j. Section 252.261; k. Section 252.264; l. Section 252.265; m. Section 252.267; n. Section 252.269(a), (b) and (c); o. Section 252.275; p. Section 252.281; q. Section 252.290 introductory text; r. Section 252.331; and s. Section 252.333.


Par. 9. Add the numbers and parentheses “(5130.6)” after the characters “1582–B” each place they occur in the following places:

a. Section 252.22; b. Section 252.36(c); c. Section 252.43(a)(1), (a)(2), (b)(1) and (b)(2); d. Section 252.222; e. Section 252.225 introductory text; f. Section 252.226; g. Section 252.227; h. Section 252.261; i. Section 252.264; j. Section 252.265; k. Section 252.267; l. Section 252.269(a) and (c); m. Section 252.275; n. Section 252.282; o. Section 252.290 introductory text; p. Section 252.295; and...
form and file it in accordance with its instructions and the procedures of this part. The procedures in parts 19, 24 or 25 of this chapter govern bonds covering distilled spirits plants, bonded wine cellars and breweries, respectively.

Par. 16. In the first sentence of §252.57 remove the words “regional director (compliance)” and add, in substitution, the words “appropriate ATF officer”.

Par. 17. In §252.59 remove the number “700” and add, in substitution the number “5120.36” each place it appears.

§§252.61, 252.62, 252.63 and 252.64 [Amended]

Par. 18. Remove the words “with the regional director (compliance)” each place they occur in the following places:

a. The first sentence of §252.61;

b. Section 252.62(a);

c. Section 252.63; and

d. The first two sentences of §252.64(a).

Par. 19. In §252.62(c) remove the words “for approval by the Director of Industry Operations (DIO)” and add, in substitution, the words “in accordance with its instructions”.

§§252.63, 252.70 and 252.73 [Amended]

Par. 20. Add the numbers and parentheses “(5100.12)” after the numbers “2736” each place they appear in the following places:

a. Section 252.63;

b. Section 252.70; and

c. Section 252.73(a).

§§252.64, 252.71, 252.72 and 252.73 [Amended]

Par. 21. Add the numbers and parentheses “(5110.67)” after the numbers “2737” each place they occur in the following places:

a. Section 252.64;

b. Section 252.71;

c. Section 252.72; and

d. Section 252.73(b).

Par. 22. In the last sentence of §252.64(b) remove the words “for approval by the regional regulatory administrator” and add, in substitution, the words “in accordance with its instructions”.

Par. 23. In the introductory text of §252.65 remove the words “by the regional regulatory administrator” and the words “with the regional regulatory administrator”.

§§252.65, 252.71, 252.72, 252.73, 252.250 and 252.331 [Amended]

Par. 24. Add the numbers and punctuation “(5110.68)” after the numbers “2738” each place they occur in the following places:

a. Section 252.65;

b. Section 252.71;

c. Section 252.72;

d. Section 252.73(b); and

e. Section 252.250 introductory text; and

f. Section 252.331.

§§252.70, and 252.73 [Amended]

Par. 25. Add the numbers and parentheses “(5120.25)” after the numbers “2734” each place they occur in the following places:

a. Section 252.70; and

b. Section 252.73(a).

§§252.71, 252.72 and 252.73 [Amended]

Par. 26. Add the numbers and parentheses “(5100.30)” after the numbers “2735” each place they occur in the following places:

a. Section 252.71;

b. Section 252.72; and

c. Section 252.73(b).

Par. 27. In the first sentence of §252.72 remove the words “regional director (compliance) in whose office the bond is on file” and add, in substitution, the words “appropriate ATF officer”.

Par. 28. In §252.92(a) remove the phrase “to the regional director (compliance) of the region in which the distilled spirits plant is located” and add, in substitution, the words “in accordance with instructions for the form”.

Par. 29. Amend §252.104 by:

a. In the third sentence by removing the words “The issuing” and adding, in substitution, the words “Such”; and

b. In the third and fourth sentences adding the numbers and parentheses “(5110.58) after the numbers “2177”.

Par. 30. In the introductory text of §252.116 remove the words “regional director (compliance) for the region in which the plant is located” and add, in substitution the words “appropriate ATF officer”.

Par. 31. Revise §252.122(a) and (b) to read as follows:

§252.122 Application or notice, ATF Form 5100.11.

(a) Export, use on vessels and aircraft, transfer to a customs bonded warehouse, and transfer to a foreign-trade zone. Where the exporter is not the proprietor of the bonded wine cellar from which the wine is to be withdrawn, the exporter must make an application on ATF Form 5100.11 for approval of the withdrawal. Where the exporter is the proprietor of the bonded wine cellar from which the wine is to be withdrawn, the exporter must, at the time of withdrawal of the wine, prepare
a notice of the withdrawal and shipment
on ATF Form 5100.11. ATF approval is not required if the exporter is the
proprietor of the bonded wine cellar
from which the wine is to be
withdrawn.

(b) Manufacturing bonded warehouse.
The proprietor of the manufacturing
bonded warehouse must make an
application on ATF Form 5100.11 to
withdraw wine without payment of tax
for transportation to and deposit in such
warehouse before withdrawal of the
wine.

§§252.195a [Removed]

Par. 37. Remove §252.195a.

§§252.198 and 252.220 [Amended]

Par. 38. Remove the words “regional
director (compliance) for the region in
which the claim for drawback of tax was
filed” and add, in substitution, the
words “appropriate ATF officer” each
place they appear in the following

a. The introductory text of §252.198;
and
b. The introductory text of §252.220.

§§252.199 and 252.220a [Amended]
Par. 39. Remove the words “regional
director (compliance) identified
thereon” and add, in substitution the
words “appropriate ATF officer” each
time they appear in the following

a. The last sentence of §252.199; and
b. The last sentence of §252.220a.

Par. 40. Revise the heading, second,
and third sentences of §252.215 to read
as follows:

§252.215 Certificate of tax determination,
Form 2605 (5120.20).

* * * The appropriate ATF officer
may require other evidence of tax
payment whenever such officer deems it
necessary. The exporter is responsible
for securing Form 2605 (5120.20),
properly executed, and submitting the
original of such form with the claim.

Par. 41. Add the numbers and
parentheses “(5120.20)” after the
number “2605” each place they occur in
the following places:

a. The first and last sentence of
§252.215;

b. The last sentence of §252.331; and

Par. 42. Remove the words “regional
director (compliance) of his region” and
add, in substitution the words “appropriate
ATF officer” each place they appear in the following

a. The introductory text of §252.225;
and
b. The last sentence of §252.227.

Par. 43. In §252.247 remove the
words “regional director (compliance)”
and add, in substitution the words
“ATF officer”.

Par. 44. Amend §252.250 by:

a. In the introductory text by
removing the words “with the regional
director (compliance) with whom the
notice and claim is filed” and adding,
in substitution, the words “appropriate
ATF officer” each place they appear; and

b. In the last sentence by removing the
words “regional director (compliance)
with whom the application, notice, or
otice and claim is filed” and adding,
in substitution, the words “appropriate
ATF officer”.

Par. 45. In the second sentence of
§252.262 remove the words “regional
director (compliance) of the region from
which the shipment was made” and
add, in substitution, the words
“appropriate ATF officer”.

Par. 46. In the first sentence of
§252.265 remove the words “regional
director (compliance) within whose
region the port of export is located” and
add, in substitution, the words
“appropriate ATF officer”.

Par. 47. In the first sentence of
§252.268 remove the words “regional
director (compliance) with whom the
application, notice, or notice and claim is
filed” and add, in substitution, the
words “as required by the instructions on the
form”.

§§252.303 and 252.317 [Amended]
Par. 48. Remove the words “with the
regional director (compliance),” and
add the numbers and parentheses
“(5620.8)” after the numbers 2635 each
place they occur from the following

a. Introductory text of §252.303; and
b. Introductory text of §252.317.

Par. 49. Amend §252.334 by:

a. Revising the first sentence to read
as follows:

§252.334 Credit allowance.

Where the credit relates to internal
revenue taxes on beer that have been
determined but not yet paid by the
claimant, the appropriate ATF officer will
notify the claimant in writing:

b. In the third sentence removing the
words “part 240” and adding, in
substitution, the words “part 24”.


Bradley A. Buckles,
Director.

Approved: March 6, 2002.

Timothy E. Skud,
Acting Deputy Assistant Secretary,
(Regulatory, Tariff and Trade Enforcement).

[FR Doc. 02–8869 Filed 4–12–02; 8:45 am]

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