

Dated: June 23, 1995.

**Andrew J. Beaulieu,**

*Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 95-16625 Filed 7-5-95; 8:45 am]

BILLING CODE 4160-01-F

## 21 CFR Part 522

### Implantation or Injectable Dosage Form New Animal Drugs; Xylazine Injection

**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 a supplemental new animal drug application (NADA) filed by Lloyd, Inc. The supplemental NADA provides for intramuscular use in *Cervidae* spp. of xylazine injection to produce sedation accompanied by a shorter period of analgesia.

**EFFECTIVE DATE:** July 6, 1995.

**FOR FURTHER INFORMATION CONTACT:** Marcia K. Larkins, Center For Veterinary Medicine (HFV-112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-0614.

**SUPPLEMENTARY INFORMATION:** Lloyd Inc., 604 West Thomas Ave., Shenandoah, IA 51601, has filed supplemental NADA 139-236, which provides for use of AnaSed® Xylazine Injection containing xylazine hydrochloride equivalent to 100 milligrams (mg) xylazine per milliliter (mL) in horses, and 20 mg/mL in dogs and cats. The supplemental NADA provides for intramuscular use of 100 mg/mL xylazine injection in *Cervidae* spp. (fallow deer, mule deer, sika deer, white-tailed deer, and elk) to produce sedation accompanied by a shorter period of analgesia. The drug is limited to use by or on the order of a licensed veterinarian.

Supplemental NADA 139-236 is approved as a generic copy of Bayer's NADA 47-956 for Rompun® (xylazine 100 mg/mL) injectable. The supplemental NADA is approved as of May 16, 1995, and the regulations are amended in 21 CFR 522.2662(b) to reflect the approval. The basis of 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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

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).

##### § 522.2662 [Amended]

2. Section 522.2662 *Xylazine hydrochloride injection* is amended in paragraph (b) by revising the statement "See 061690 in § 510.600(c) of this chapter for use in horses, dogs, and cats" by adding after "horses" the words "wild deer, elk,".

Dated: June 28, 1995.

**Andrew J. Beaulieu,**

*Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 95-16626 Filed 7-5-95; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### Office of the Secretary

#### 24 CFR Part 791

[Docket Numbers R-95-1637, R-95-1728; FR-3658-F-03]

RIN 2501-AB71

#### Allocation of Budget Authority for Housing Assistance

**AGENCY:** Office of the Secretary, HUD.

**ACTION:** Final rule.

**SUMMARY:** This rule makes final two interim rules previously published by HUD which amended HUD regulations governing allocation of budget authority for housing assistance. The previous interim rules added two subcategories of budget authority for uses that the Secretary determines are incapable of geographic allocation by formula, and increased the amount of funding available under the Headquarters Reserve. In addition, this final rule also adds two technical amendments to HUD's regulations governing the allocation of budget authority for housing assistance.

**EFFECTIVE DATE:** This final rule is effective on August 7, 1995.

**FOR FURTHER INFORMATION CONTACT:** For the Public and Indian Housing program, and section 8 voucher, certificate, and moderate rehabilitation programs, Nanci Gelb, Director, Budget Division, Room 4230, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410-0500, telephone (202) 708-0920. Hearing- or speech-impaired individuals may call HUD's TDD number (202) 708-0850. For other assisted housing programs, Joel Balsham, Program Advisor, Office of the Deputy Assistant Secretary for Multifamily Housing, Room 6124, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410-8000, telephone (202) 708-4135. Hearing- or speech-impaired individuals may call HUD's TDD number (202) 755-4594. (These are not toll-free numbers.)

#### SUPPLEMENTARY INFORMATION:

##### I. Background

This rule finalizes two previously published interim rules amending HUD's regulations governing allocation of budget authority. The first rule, published on August 4, 1993 (58 FR 41426), added two subcategories of budget assistance to § 791.403 for uses that the Secretary determines are incapable of geographic allocation by formula: (1) Budget authority as identified in the Operating Plan submitted to the Appropriations Committees; and (2) Budget authority involving recently enacted legislation which prescribes that a portion of program assistance be set aside or otherwise mandated for other than general use. The second rule, published on July 11, 1994 (59 FR 35253), increased the amount of funding available under the Headquarters Reserve.

#### A. August 4, 1993 Interim Rule

The first subcategory added by the August 4, 1993, interim rule was budget authority as identified in the Operating Plan submitted to the Appropriations Committees. The "Operating Plan" is presented annually to the Appropriations Committees to reflect changes from the budget originally submitted to the Congress by the Administration. Its history dates back to 1987 when the Conference Report accompanying H.J. Res. 395, "Making Further Continuing Appropriations for the Fiscal Year Ending September 30, 1988," stated that "because of the substantial changes in many accounts from the budget estimates (including a number of general reductions), the conferees direct that [HUD and the Independent Agencies covered in the same appropriation] submit a fiscal year 1988 operating plan by February 1, 1988." H.R. Rep. 100-498 (Dec. 22, 1987), at 837. The statement added that "the conferees expect such operating plans to include recommended changes from the budget estimates except that no reductions may be proposed in programs, projects, or activities for which funding has been added by the Congress." Ever since that time, the Department has furnished the Committees an Operating Plan annually which identifies changes from published estimates, including reprogramming within amounts set out in the Conference Report table.

The August 1993 interim rule also added a second subcategory of budget authority incapable of geographic allocation by formula consisting of recently enacted legislation which prescribes that a portion of program assistance be set aside or otherwise mandated for other than general use. Recent HUD authorization statutory amendments contain provisions which have the effect of specifically targeting appropriated funds. For example, section 101(b) of the Housing and Community Development Act of 1992, Pub.L. 102-550 (Oct. 28, 1992), amended the United States Housing Act of 1937 to require funding of \$20 million in both FY 1993 and FY 1994 for section 8 15 year contracts for project-based assistance to be used for a multi-cultural tenant empowerment and homeownership project located in the District of Columbia. This assistance obviously is incapable of geographic allocation by formula because it is expressly authorized for one city only.

In the first year following enactment of set-asides like the one described immediately above, the Operating Plan could be expected to address these

newly established purposes. In subsequent years, however, they would have been incorporated in the Department's budget. For that reason, the interim rule also added to § 791.403(b)(ii) the subcategory of assistance included in an authorization statute, such as set-asides, where the Secretary determines that such assistance is incapable of geographic allocation by formula.

#### B. July 11, 1994 Interim Rule

The interim rule published on July 11, 1994 (59 FR 35253), increased the amount of funding available under the Headquarters Reserve. In the preamble of that rule, HUD explained that it was further implementing section 213(d) of the Housing and Community Development Act of 1974, as amended, 42 U.S.C. 1439(d), so as to maximize flexibility in the provision of the Headquarters Reserve authorized under section 213(d)(4) of the Act.

Section 213(d)(4) permits the Secretary of HUD to retain not more than five percent of the financial assistance that becomes available under all programs authorized under the United States Housing Act of 1937 (except for public housing operating subsidy under section 9 and modernization funding under section 14). Prior to the July 11, 1994, interim rule, the Headquarters Reserve at § 791.407 was more delimited—it only permitted a Headquarters Reserve of five percent of the total amount of budget authority which is "fair shared" pursuant to part 791, subpart D. The effect of the regulatory limitation was to narrow considerably the base upon which the five percent Reserve was calculated, as compared to what the statute permits.

The July 11, 1994, interim rule expanded the base by including not only the amount of funding which is fair shared pursuant to the formula at § 791.403(b)(2), but also all budget authority allocated for uses that the Secretary determines are incapable of geographic formula, as spelled out at § 791.403(b)(1). Examples of the latter category include amendments of existing contracts, renewals of assistance contracts, the section 8 loan management and property disposition accounts, assistance earmarked by the Congress in appropriation law line items, and uses of budget authority identified in the Department's Operating Plan submitted to the Appropriations Committee.

While the interim rule increased the amount of funding available under the Headquarters Reserve, it did not change the limited statutory purposes for which

funding may be used. Headquarters Reserve funding can only be used for unforeseen housing needs resulting from natural and other disasters; housing needs resulting from emergencies, as certified by the Secretary, other than such disasters; housing needs resulting from the settlement of litigation; and housing in support of desegregation efforts.

As we stated in the preamble of the July 11, 1994, interim rule, because the incidence of these types of housing assistance funding are unpredictable, the availability of readier resources through an increased Reserve is one which HUD will only call upon as needed. Although a greater amount of budget authority is now available under current regulations, HUD may not use the full statutory maximum in any particular year. The draw upon the Reserve will be carefully tempered to exigencies and real, immediate need.

Finally, as noted in the interim rule, the base upon which the Headquarters Reserve is calculated does not include the section 202 program of supportive housing for the elderly. Section 801(b) of the Cranston-Gonzalez National Affordable Housing Act (NAHA) removed the section 202 program from coverage under section 213(d). However, NAHA did not repeal a previous amendment to section 213(d)(1)(A)(i) made by section 101 of the Department of Housing and Urban Development Reform Act of 1989 (Reform Act). The Reform Act amendment requires that section 202 assistance be allocated in a manner that ensures that awards of that assistance are made for projects of sufficient size to accommodate facilities with supportive services appropriate to the needs of frail elderly residents. Moreover, the Department has elected to continue the fair sharing of section 202 housing assistance in order to promote fair and balanced geographic diversity. (The fair sharing formula for section 202 assistance is specifically tailored at § 791.402(c)(1) to reflect relevant characteristics of the elderly population.) Notwithstanding this retention of section 202 allocations in part 791, and the continued policy of fair sharing section 202 housing assistance, the statutory range for calculation of the five percent Headquarters Reserve is limited to programs under the United States Housing Act of 1937 which are covered by section 213(d).

#### C. Conforming Changes in Today's Final Rule

In addition to finalizing changes made in the two previously published interim

rules, this rule adds several conforming changes to part 791. First, because the section 202 elderly housing program is no longer a loan program, the reference to that effect is removed from § 791.401. Second, because section 101 of the Reform Act eliminated the statutory requirement of between 20 and 25 percent of non-metropolitan area funding, insofar as it had applied to the Headquarters Reserve, it is being deleted from § 791.403(a). Third, because of the Department's reorganization which specifically eliminated the former Regions, Regional Administrators, Field Office Managers, and the functions previously performed by them, technical revisions are made to §§ 791.403(b)(2) and 791.405 to replace certain nomenclatures.

## II. Discussion of Public Comment

The Department did not receive any public comments in response to the August 4, 1993, interim rule. The Department received two public comments in response to the July 11, 1994, interim rule. The first comment was from the Housing Authority of the City of Los Angeles which expressed its support of the rule, especially as it enhances the Secretary's ability to respond to unique disaster and emergency situations. The second comment was from the Oklahoma Housing Authority which urged consideration of three factors. First, the commenter stated that there is often no available housing when emergency funding is needed, so that HUD should consider purchasing modular-type housing rather than providing section 8 certificates. Neither this rule, nor its statutory authorization at section 213 of the Housing and Community Development Act of 1974, as amended, permits substitution of other resources for section 8 certificates, so that the alternative proposed by the commenter would not be viable in this context.

This commenter further stated that HUD should consider the impact on portability when additional certificates are placed within a community. The Department acknowledges that relative unavailability of housing in a jurisdiction may result in utilization of portability to locate housing in other areas. Nevertheless, the purpose of the disaster and emergency set-aside authority is to provide relief for persons and families who are adversely affected by these conditions and who will utilize the assistance in a manner most efficacious to them.

Finally, this commenter contended that the funding set-aside should be motivated completely by need. The Department agrees with this comment.

In the preamble of the interim rule, HUD stated that, "[t]he draw upon the Reserve will be carefully tempered to exigencies and real, immediate need." However, no regulatory text change is necessary to incorporate this argument.

## III. Other matters

### A. Executive Order 12866

This rule was reviewed by the Office of Management and Budget (OMB) under Executive Order 12866 on Regulatory Planning and Review, issued by the President on September 30, 1993. Any changes made in the rule subsequent to its submission to OMB are identified in the docket file, which is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays, at the office of the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410-0500.

### B. Regulatory Flexibility Act

The Secretary in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed and approved this rule, and in so doing certifies that this rule does not have a significant economic impact on a substantial number of small entities. The rule revises existing procedures for the allocation of housing assistance funds and for local government and HUD review of applications for housing assistance, but will make no change in the economic impact of these procedures on small entities.

### C. Environmental Impact

In accordance with 40 CFR 1508.4 of the regulations of the Council on Environmental Quality and 24 CFR 50.20(k) of the HUD regulations, the policies and procedures contained in this rule relate only to internal administrative procedures whose content does not constitute a development decision nor affect the physical condition of project areas or building sites, and therefore, are categorically excluded from the requirements of the National Environmental Policy Act.

### D. Executive Order 12612, Federalism

The General Counsel, as the Designated Official under section 6(a) of Executive order 12612, *Federalism*, has determined that the policies contained in this rule will not have substantial direct effects on states or their political subdivisions, or the relationship between the Federal government and the states, or on the distribution of power and responsibilities among the

various levels of government. Specifically, this rule will not substantially alter the established roles of HUD and the States and local governments, including PHAs, in administering the affected programs. As a result, the rule is not subject to review under the order.

### E. Executive Order 12606, The Family

The General Counsel, as the Designated Official under Executive Order 12606, *The Family*, has determined that this rule does not have potential for significant impact on family formation, maintenance, and general well-being, and, thus, is not subject to review under the Order. No significant change in existing HUD policies or programs will result from promulgation of this rule, as those policies and programs relate to family concerns.

### F. Regulatory Agenda

This rule was listed as item number 1389 in the Department's Semiannual Agenda of Regulations published on May 8, 1995 (60 FR 23368, 23380) in accordance with Executive Order 12866 and the Regulatory Flexibility Act.

### G. Justification for Final Rulemaking

In general, the Department publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking, 24 CFR part 10. However, part 10 does provide for exceptions from that general rule where the agency finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when prior public procedure is "impracticable, unnecessary, or contrary to the public interest." (24 CFR 10.1)

The Department finds that good cause exists to publish this rule for effect without first soliciting public comment, because prior public procedure is unnecessary. The two changes added to this final rule (discussed above in section I(c) of the preamble) are merely technical, conforming changes.

### H. The Catalog of Federal Domestic Assistance program numbers are as follows:

- 14.103 Interest Reduction Payments—Rental and Cooperative Housing for Lower Income Families
- 14.149 Rent Supplements—Rental Housing for Lower Income Families
- 14.156 Lower Income Housing Assistance Program (Section 8)
- 14.157 Housing for the Elderly or Handicapped
- 14.177 Housing Voucher Program
- 14.850 Public and Indian Housing

14.851 Low Income Housing—  
Homeownership Opportunities for  
Low Income Families

**List of Subjects in 24 CFR Part 791**

Grant programs—housing and  
community development, Indians,  
Intergovernmental relations, Public  
housing, Rent subsidies.

Accordingly, 24 CFR part 791 is  
amended as follows:

**PART 791—REVIEW OF  
APPLICATIONS FOR HOUSING  
ASSISTANCE AND ALLOCATIONS OF  
HOUSING ASSISTANCE FUNDS**

1. The authority citation for 24 CFR  
part 791 is revised to read as follows:

**Authority:** 42 U.S.C. 1439 and 3535(d).

2. Section 791.401 is revised to read  
as follows:

**§ 791.401 General.**

This subpart establishes the  
procedures for allocating budget  
authority under section 213(d) of the  
Act for the programs identified in  
§ 791.101(a). It describes the allocation  
of budget authority by the appropriate  
Assistant Secretary to the applicable  
Program Office Director in the HUD  
State or Area Office, and by the Program  
Office Director to allocation areas  
within the HUD State or Area Office  
jurisdiction.

3. Section 791.403 is amended by  
revising paragraphs (a), (b)(1)(ii), and  
(b)(2), to read as follows:

**§ 791.403 Allocation of housing  
assistance.**

(a) The Assistant Secretary for  
Housing and the Assistant Secretary for  
Public and Indian Housing shall confer  
to determine how the available budget  
authority is to be allocated. The total  
budget authority available for any fiscal  
year shall be determined by adding any  
available, unreserved budget authority  
from prior fiscal years to any newly  
appropriated budget authority for each  
housing program. On a nationwide  
basis, at least 20 percent, but not more  
than 25 percent, of the total budget  
authority available for any fiscal year,  
which is allocated pursuant to  
paragraph (b)(2) of this section, shall be  
allocated for use in non-metropolitan  
areas.

(b) \* \* \*

(1) \* \* \*

(ii) Assistance which is—

(A) The subject of a line item  
identification in the HUD  
appropriations law, or in the table  
customarily included in the Conference  
Report on the appropriation for the

Fiscal Year in which the funds are to be  
allocated;

(B) Reported in the Operating Plan  
submitted by HUD to the Committees on  
Appropriations; or

(C) Included in an authorization  
statute where the nature of the  
assistance, such as a prescribed set-  
aside, is, in the determination of the  
Secretary, incapable of geographic  
allocation by formula,

\* \* \* \* \*

(2) Budget authority remaining after  
carrying out allocation steps outlined in  
paragraph (b)(1) of this section shall be  
allocated in accordance with the  
housing needs percentages calculated  
under § 791.402 (b), (c), (d), and (e).  
HUD may allocate assistance under this  
paragraph in such a manner that each  
State shall receive not less than one-half  
of one percent of the amount of funds  
available for each program referred to in  
§§ 791.101(a) in each fiscal year. If the  
budget authority for a particular  
program is insufficient to fund feasible  
projects, or to promote meaningful  
competition at the State/Area Office  
level, budget authority may be allocated  
among the ten geographic Areas of the  
country. The funds so allocated will be  
assigned by Headquarters to the State/  
Area Office(s) with the highest ranked  
applications within the ten geographic  
Areas.

\* \* \* \* \*

4. Section 791.405 is revised to read  
as follows:

**§ 791.405 Reallocations of budget  
authority.**

(a) The State/Area Office shall make  
every reasonable effort to use the budget  
authority made available for each  
allocation area within such area. If the  
Program Office Director determines that  
not all of the budget authority allocated  
for a particular allocation area is likely  
to be used during the fiscal year, the  
remaining authority may be allocated to  
other allocation areas where it is likely  
to be used during that fiscal year.

(b) If the Assistant Secretary  
determines that not all of the budget  
authority allocated to a State/Area  
Office is likely to be used during the  
fiscal year, the remaining authority may  
be reallocated to another State/Area  
Office where it is likely to be used  
during the fiscal year.

(c) Any reallocations of budget  
authority among allocation areas or  
State/Area Offices shall be consistent  
with the assignment of budget authority  
for the specific program type and  
established set-asides.

(d) Notwithstanding the requirements  
of paragraphs (a) through (c) of this  
section, budget authority shall not be

reallocated for use in another State  
unless the appropriate Program Office  
Director or the Assistant Secretary has  
determined that other allocation areas  
within the same State cannot use the  
available authority during the fiscal  
year.

5. Section 791.407 is amended by  
revising the introductory text of  
paragraph (a) to read as follows:

**§ 791.407 Headquarters Reserve.**

(a) A portion of the budget authority  
available for the housing programs  
listed in § 791.101(a), not to exceed an  
amount equal to five percent of the total  
amount of budget authority available for  
the fiscal year for programs under the  
United States Housing Act of 1937 listed  
in § 791.101(a), may be retained by the  
Assistant Secretary for subsequent  
allocation to specific areas and  
communities, and may only be used for:

\* \* \* \* \*

Dated: June 27, 1995.

**Henry G. Cisneros,**  
*Secretary.*

[FR Doc. 95-16489 Filed 7-5-95; 8:45 am]  
BILLING CODE 4210-32-P

**DEPARTMENT OF TREASURY**

**Fiscal Service**

**31 CFR Part 321**

**Payments by Banks and Other  
Financial Institutions of United States  
Savings Bonds and United States  
Savings Notes (Freedom Shares)**

*CFR Correction*

In Title 31 of the Code of Federal  
Regulations, parts 200 to end, revised as  
of July 1, 1994, on page 190, paragraph  
16 of the appendix to part 321 was  
incorrectly revised. Paragraphs (a)  
through (e) following paragraph 16  
should have been removed.

BILLING CODE 1505-01-D

**DEPARTMENT OF TRANSPORTATION**

**National Highway Traffic Safety  
Administration**

**49 CFR Part 571**

[Docket No. 74-09; Notice 42]

RIN 2127-AF02

**Federal Motor Vehicle Safety  
Standards; Child Restraint Systems**

**AGENCY:** National Highway Traffic  
Safety Administration (NHTSA),  
Department of Transportation.