Act are limited to the operation of aircraft in flight.

One comment requested that the proposal be broadened to include aircraft movement other than taxiing (such as the towing of aircraft) and to include persons other than pilots. In order not to exceed the scope of Notice 74–13, this amendment is limited to pilots and to the taxiing of aircraft.

(Secs. 307 and 313(a), Federal Aviation Act of 1958 (49 U.S.C. §§ 1348, and 1354(a)); sec. 6(c), Department of Transportation Act (49 U.S.C. § 1655(c)))

In consideration of the foregoing, Part 91 of the Federal Aviation Regulations is amended, effective August 18, 1975, by amending § 91.87(h) to read as follows:

§ 91.87 Operation at airports with operating control towers.

* * * * *

(h) *Clearances required.* No pilot may, at an airport with an operating control tower, taxi an aircraft on a runway or taxiway, or takeoff or land an aircraft, unless he has received an appropriate clearance from ATC. A clearance to "taxi to" the runway is a clearance to cross all intersecting runways but is not a clearance to "taxi on" the assigned runway.

Issued in Washington, D.C. on July 3, 1975.

J. W. COCHRAN,
Acting Administrator.

[FR Doc.75-18301 Filed 7-14-75;8:45 am]

Title 15—Commerce and Foreign Trade

CHAPTER III—DOMESTIC AND INTERNATIONAL BUSINESS ADMINISTRATION, DEPARTMENT OF COMMERCE

SUBCHAPTER B—EXPORT REGULATIONS

PART 377—SHORT SUPPLY CONTROLS

Method of Licensing Exports of Petroleum Products in the Third Quarter 1975

The licensing system used in the second quarter 1975 for the export of petroleum products other than crude oil is generally continued on the same basis during the third quarter 1975, except that the base period for determining exporters' shares of quota entitlements for Commodity Group I (Butane, propane, and natural gas liquids) is changed to July 1, 1972 through September 30, 1972. This change in the base period is made to conform to that used in the mandatory allocations program of the Federal Energy Administration, which recognizes seasonal fluctuations in the use of these products. All other product quotas, as in the past, are to be calculated on a base period average spanning 1971, 1972, and the first six months of 1973.

As during the second quarter 1975, carbon-black feedstock oils (Commodity Group H) will not be subject to quota limitations, but will be subject to validated export licensing. Consignees of carbon-black feedstock oils must be established users of this product as a petrochemical feedstock in the manufacture of carbon-black. Also, exporters of carbon-black feedstock oils are required to submit certain additional documentation as described in § 377.6(e)(4) to support an application for export license.

The policy for the export of crude oil will remain the same as that announced in Export Administration Bulletin No. 114 of April 18, 1974.

The country quotas for each Petroleum Commodity Group that will be available during the third quarter 1975 are announced in Supplement No. 2 to Part 377 of the Export Administration Regulations and contained herein. As previously, 5 percent of the overall quota for each Commodity Group will be reserved for contingencies and the announced country quotas represent 95 percent of the overall authorized exports. All licenses issued during the third quarter 1975 will expire 30 days after the end of the calendar quarter. Requests for extension of the validity period of such licenses normally will not be entertained.

Accordingly, Supplement No. 2 to Part 377 of the Export Administration Regulations (15 CFR Part 377) is revised to read as follows:

SUPPLEMENT NO. 2—PETROLEUM AND PETROLEUM PRODUCTS SUBJECT TO SHORT SUPPLY LICENSING CONTROLS

Schedule B number	*Commodity description*
	Petroleum Licensed Only in Accordance With § 377.6(d)(1)
	GROUP A
331.0100	Crude petroleum
331.0200	Petroleum partly refined for further refining
	Petroleum Products Subject to Historical Quotas
	GROUP B
332.1015	Aviation gasoline
	GROUP C
332.1030	Gasoline, n.e.c.
332.1050	Gasoline blending agents, hydrocarbon compounds only, n.e.c.
	GROUP D
332.2010	Kerosene, except kerosene-type jet fuel
	GROUP E
332.2020	Jet fuel
	GROUP F
332.3000	Distillate fuel oils
	GROUP G
332.4000	Residual fuel oils
	GROUP I
341.1025	Butane
341.1030	Propane
341.1040	Natural gas liquids, including LPG, n.e.c.
	Petroleum Products Not Subject to Quotas
	GROUP H
332.9160	Carbon black feedstock oil

Quantities: Report the above commodities in barrels of 42 gallons.

Shipping tolerance: 10 percent.

Submission dates: Not prior to the beginning of the applicable quarter, and not later than:

	3rd quarter 1975
Historical exporters of petroleum commodities other than crude oils.	Sept. 20, 1975.
Hardships, crude oil exporters, and carbon black feed-stock oil exporters.	At any time.

COUNTRY QUOTAS FOR GROUP B

(Schedule B No. 332.1015, Aviation Gasoline)

Country:	*Quota (barrels)*
Bahamas	1,676
Belgium	78
Bolivia	2,761
Cameroon	65
Canada	3,313
Dahomey	58
French Pacific Islands	3,853
Gabon	115
Holland	18,940
Honduras	307
India	12,743
Ivory Coast	98
Mexico	10,509
Singapore	14,783
All other countries	165

COUNTRY QUOTAS FOR GROUP C

(Schedule B No. 332.1030, Gasoline, n.e.c.)

(Schedule B No. 332.1050, Gasoline blending agents, hydrocarbon compounds only, n.e.c.)

Country:	*Quota (barrels)*
Australia	554
Austria	139
Bahamas	872
Belgium	3,929
Brazil	29,061
Canada	76,078
Denmark	76
Finland	162
France	635
French Pacific Islands	18,523
Holland	48,039
India	143
Iran	106
Italy	314
Japan	299
Leeward & Windward Islands	1,109
Mexico	149,791
Mozambique	66
Nigeria	143
Philippines	137
South Africa	556
Sweden	56
United Kingdom	3,111
Venezuela	165
West Germany	3,966
All other countries	513

COUNTRY QUOTAS FOR GROUP D

(Schedule B No. 332.2010, Kerosene, except kerosene-type jet fuel)

Country:	*Quota (barrels)*
Australia	1,118
Brazil	150
Canada	1,667
Chile	122
Congo	56
Egypt	88
France	59
French Pacific Islands	3,046
Gabon	266
Holland	349
Israel	586
Italy	467
Japan	2,354

Country:	Quota (barrels)
Mexico	72
Nigeria	740
Peru	71
Philippines	89
Singapore	442
South Africa	371
United Kingdom	9,391
Venezuela	454
West Germany	7,047
All other countries	252

COUNTRY QUOTAS FOR GROUP E

(Schedule B No. 332.2020, Jet Fuel)

Country:	Quota (barrels)
Bahamas	31
Canada	42,797
Mexico	48,794

COUNTRY QUOTAS FOR GROUP F

(Schedule B No. 332.3000, Distillate fuel oils)

Country:	Quota (barrels)
Bahamas	3,125
Canada	98,156
Colombia	36,385
Denmark	22,413
French Pacific Islands	10,086
Holland	58,895
Japan	11,636
Mexico	190,448
Netherlands Antilles	34,072
Peru	13,577
Surinam	327
All other countries	1,359

COUNTRY QUOTAS FOR GROUP G

(Schedule B No. 332.4000, Residual fuel oils)

Country:	Quota (barrels)
Bahamas	110,780
Barbados	11,275
Belgium	12,865
Brazil	63,662
Canada	833,224
Canary Islands	14,182
Denmark	32,003
France	2,493
French Pacific Islands	16,967
Greece	19,798
Holland	50,108
Ireland	11,626
Italy	181,979
Jamaica	152,086
Japan	266,105
Leeward & Windward Islands	12,745
Mexico	643,500
Netherlands Antilles	99,078
Panama	74,793
Peru	30,821
Poland	2,070
Singapore	15,455
South Africa	21,432
Spain	36,283
Sweden	75,413
United Kingdom	227,631
All other countries	814

COUNTRY QUOTAS FOR GROUP I

(Schedule B No. 341.1025, Butane)

(Schedule B No. 341.1030, Propane)

(Schdeule B No. 341.1040, Natural gas liquids)

Country:	Quota (barrels)
Canada	18,651
Mexico	2,413,904
Netherlands	10,927
Japan	221,346
New Zealand	1,041
Guatemala	466
All other	4,616

Base period: The base period for determining historical quota shares for group I commodities in the third quarter 1975 is the period from July 1, 1972 to September 30, 1972.

Effective date of action: July 3, 1975.

RAUER H. MEYER,
Director,
Office of Export Administration.

[FR Doc.75-18217 Filed 7-14-75;8:45 am]

Title 20—Employee's Benefits

CHAPTER III—SOCIAL SECURITY ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Regs. No. 5]

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Health Maintenance Organizations; Qualifying Conditions

Correction

In FR Doc.75-16867 appearing at page 28016, in the issue for Wednesday, July 2, 1975, the following corrections should be made:

1. On page 28018 in the second column, the next to the last line in § 405.2001(b)(4) should read: "covered items and services to its title XVIII beneficiaries."

2. In § 405.2001(b)(5)(i) in the second column on page 28018, the third line should read: "marily through physicians who are em-".

3. In the third column on page 28018, the third line of § 405.2001(b)(5)(ii) should read: "marily through independent practition-".

4. On page 28020 in the first column, in § 405.2005(a)(3)(i), the eleventh line should read: "patient. Such services must be or must appear".

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[FRL 399-8; FAP5H5061/R9]

PART 561—TOLERANCES FOR PESTICIDES IN ANIMAL FEEDS ADMINISTERED BY ENVIRONMENTAL PROTECTION AGENCY

Thiabendazole

On September 27, 1974, notice was given (39 FR 34706) that Merck, Sharp & Dohme, Rahway NJ 07065 had filed a food additive petition (FAP 5H5061) with the Environmental Protection Agency (EPA). This petition proposed the establishment of a food additive tolerance for residues of the fungicide thiabendazole (2 - (4 - thiazolyl) benzimidazole) in potato processing waste at 30 parts per million resulting from concentration and carry-over following post-harvest application of the fungicide to potatoes. [A related document on thiabendazole and the establishment of a pesticide tolerance appeared in the FEDERAL REGISTER on June 17, 1975 (40 FR 25591).]

The data submitted in the petition and other relevant material have been evaluated. It is concluded that the tolerance should be established to cover residues resulting from both pre- and post-harvest applications. The tolerance established by amending the regulation (21 CFR 561.380) will protect the public health.

Any person adversely affected by this regulation may on or before August 14, 1975 file written objections with the Hearing Clerk, Environmental Protection Agency, 401 M Street SW, East Tower, Room 1019, Washington D.C. 20460. Such objections should be submitted in quintuplicate and specify the provisions of the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

Effective July 15, 1975, Part 561, Subpart A, is amended by revising § 561.380 as set forth below.

Dated: July 8, 1975.

(Sec. 409(c)(1) and (4), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(1) and (4)), transferred to Administrator EPA in Reorganization Plan No. 3 (35 FR 15623))

EDWIN L. JOHNSON,
Deputy Assistant Administrator,
for Pesticide Programs.

Section 561.380 is amended by adding the new paragraph "30 parts per million * * *" after the paragraph "33 parts per million * * *" to read as follows:

§561.380 Thiabendazole.

* * * * *

30 parts per million in potato processing waste resulting from pre- and post-harvest applications to the raw agricultural commodity potatoes.

* * * * *

[FR Doc.75-18207 Filed 7-14-75;8:45 am]

SUBCHAPTER F—BIOLOGICS

[Docket No. 75N-0022]

TEST FOR HEPATITIS B SURFACE ANTIGEN

The Commissioner of Food and Drugs is amending the biologics regulations, effective September 15, 1975, (1) to require that all references to "hepatitis associated (Australia) antigen" and "hepatitis associated antibody (anti-Australia Antigen)" be changed to "hepatitis B surface antigen (HB_sAg)", and "antibody to hepatitis B surface antigen (Anti-HB_s)," respectively, (2) to require that the testing for the presence of Hb_sAg of all donations of human blood, plasma, and serum to be used in preparing biological products be performed using only those reagents which are most sensitive in their capacity to detect such antigen, and (3) to restrict the use of source blood, plasma, or serum that is reactive to hepatitis B surface antigen to the very few situations in which final products can be prepared only from hepatitis B surface antigen positive source material. This amendment of the regulations is based on two proposals

published in the FEDERAL REGISTER on July 9, 1974 (39 FR 25233) and July 17, 1974 (39 FR 26161), respectively.

In the July 9, 1974 proposal, the Commissioner proposed to amend § 610.40 Test for hepatitis associated (Australia) antigen (21 CFR 610.40) to require that all donations of human blood, plasma, or serum to be used in preparing a biological product shall be tested for hepatitis B antigen by a method of at least third generation sensitivity, which is the most sensitive method currently available. In addition, it was proposed that all references to "hepatitis associated (Australia) antigen" in Parts 610, 640, and 660 be changed to "hepatitis B antigen and that a phrase in § 610.40(a) applicable to material collected prior to the effective date of that section be deleted since it was assumed that all such products had been expended. Interested persons were given until September 9, 1974 to file written comments concerning this proposal.

The July 17, 1974 proposal primarily concerned the amendment of certain sections of the regulations governing Source Plasma (Human). As part of this proposal for Source Plasma (Human), the Commissioner also proposed to amend paragraph (b)(2) of § 610.40 to strengthen the existing limitations on the use of blood, plasma, or serum that is reactive when tested for the hepatitis B antigen and intended for use as source material in the further manufacture of licensed in vitro diagnostic biological products. In addition, the Commissioner concluded that the regulations should be expanded to include unlicensed in vitro diagnostic biological products which are prepared from licensed source material and therefore he proposed to add a new paragraph (b)(3) to § 610.40. Interested persons were given until August 16, 1974 to file written comments concerning this proposal.

In view of the relationship between the July 9, 1974 proposal and portions of the July 17, 1974 proposal, the Commissioner has concluded that the most practical manner in which to proceed to a final order would be to address these issues in one document.

Since the inception of required hepatitis testing on July 1, 1972, the sensitivity of the testing reagents has been increased as a result of continuing research to develop a rapid and more sensitive HB_sAg testing method. The relative sensitivity of currently available test methods is measured by reference to the capacity of the antibody to hepatitis B surface antigen (Anti-HB_s) to detect HB_sAg positive samples in the Bureau of Biologics reference panel of antigen-positive sera, each of which contains varying amounts of HB_sAg. In common terminology, a first generation test is one which is capable of detecting those antigen-positive sera designated "A" in the reference panel; a second generation test detects those antigen-positive sera designated "A," (A) and "B"; and a third generation test detects all antigen-positive sera designated "A", (A), "B", (B), and "C".

There are presently two methods with third generation sensitivity available on the market. The more sensitive of the two is the radioimmunoassay (RIA) method, while one of almost comparable sensitivity is the reversed passive hemagglutination test (RPHA).

The Commissioner has concluded that only testing methods of third generation sensitivity should be employed to test for the presence of HB_sAg in human blood, plasma, or serum as part of the continuing effort to eliminate the contamination of biological products derived from human blood with infectious hepatitis B virus.

Twenty-six letters, containing varying numbers of comments regarding the July 9, 1974 proposal, were received. Three letters supported the entire proposal. The remaining 23 letters, although generally in favor of utilizing the more sensitive method of HB_sAg testing, offered a number of specific comments. Five comments were received pertaining to the proposed amendments to the hepatitis testing requirements set forth in the July 17, 1974 proposal regarding Source Plasma (Human). The comments received and the Commissioner's responses are discussed below.

Numerous editorial changes have been made in § 610.40 in the final regulation, lengthening it considerably. For clarification, § 610.40 has been divided into five paragraphs rather than two paragraphs as proposed. For the convenience of the reader, each of the following paragraphs of the preamble will refer to the section designation as proposed, followed in parenthesis by the section as redesignated in the final regulation.

1. Five comments suggested that the final regulation use the nomenclature as adopted by the Committee on Viral Hepatitis of the National Academy of Sciences/National Research Council for hepatitis B antigen and antibody. The nomenclature adopted by the committee for the antigen is "hepatitis B surface antigen (HB_sAg)" and for the antibody it is "antibody to hepatitis B surface antigen (Anti-HB_s)."

The Commissioner concurs with the suggestion to adopt the new terminology. In view of the increasing growth of knowledge regarding the complexity of the hepatitis B surface antigen, it is prudent to utilize standard nomenclature at an early time to minimize confusion when referring to such antigen and its corresponding antibody. Therefore, the final regulation is amended to employ the terminology of "hepatitis B surface antigen" and "antibody to hepatitis B surface antigen" where applicable.

2. Two of the five comments above also suggested that review and acceptance by the Bureau of Biologics of the revised labeling necessitated by the change in terminology, as required by § 601.6(b) (21 CFR 601.6(b)), be deferred so that labels with the new nomenclature could be put into use more quickly.

The Commissioner concurs with the suggestion that review and acceptance by the Bureau of Biologics of labeling changes before use be waived in those instances in which the labeling change for blood and blood products concerns only the statement on the label that the test for the hepatitis B surface antigen was performed and the result of the test. However, the Commissioner advises that all licensed establishments are required to submit to the Bureau of Biologics a copy of the labeling stating the new nomenclature so that a complete and current license file of each establishment is maintained. If additional information on the label is revised, other than that regarding hepatitis testing, the label must be submitted to the Bureau of Biologics for review and acceptance before use. All label revisions may use the abbreviations of "HB_sAg" and "Anti-HB_s" when referring to the hepatitis B surface antigen and its corresponding antibody, respectively.

3. One comment suggested that each manufacturer be permitted to deplete current supplies of labels before converting to labels with the new terminology.

The Commissioner disagrees with the suggestion that each manufacturer be permitted to exhaust his current supply of labels before changing to the new nomenclature. Such a procedure is contrary to the desired objective of achieving an early conversion to standard hepatitis nomenclature. Inasmuch as different establishments will have varying amounts of labeling stock on hand, a definite period for conversion to standard labeling must be established, otherwise the complete conversion to standard nomenclature may require years to accomplish. The Commissioner has, therefore, concluded that all applicable labeling of blood and blood products shall be appropriately modified within 12 months of the effective date of this regulation or when current supplies are exhausted, whichever date occurs first.

4. The Commissioner's acceptance of new terminology for the antibody to hepatitis B surface antigen constitutes a change in the proper name of a licensed biological in vitro diagnostic reagent. Such a change will necessitate revision of labels, package inserts, and literature by the manufacturers of the licensed product.

The Commissioner is aware of the expense and time such labeling changes entail, but believes that these factors are not sufficiently persuasive to justify delay in implementation of standard labeling terminology. Therefore, the final regulation amends Subpart A of Part 660 Additional Standards for Diagnostic Substances for Laboratory Tests to change the proper name of the licensed in vitro diagnostic product used to detect the presence of HB_sAg from "Hepatitis Associated Antibody (Anti-Australia Antigen)" to "Antibody to Hepatitis B Surface Antigen." A period of 12 months from the effective date of this order is also provided as the time in which the appropriate labeling revisions must be completed.

5. Nine comments regarding § 610.40 (a) General (redesignated § 610.40(c)

Materials in storage) objected to the removal of the provision that material collected and stored before the effective date (July 1, 1972) of the initial regulation that required hepatitis testing, be tested upon removal from storage by the manufacturer. The comments indicated that there are manufacturers who have material in storage that was collected before July 1, 1972, and was not tested for HB_sAg, but that such material could and should be tested upon removal from storage.

Since the proposal to remove the provision was based upon an assumption that all such untested stored material had been expended, and this does not appear to be the case, the Commissioner concurs with the comments. The final regulation, therefore, retains the provision for testing material, by a method of third generation sensitivity, collected prior to July 1, 1972 for the presence of HB_sAg before use as a biological product, or before being used in the manufacture of a biological product.

6. Six of the above nine comments also requested clarification regarding the applicability of the new and more sensitive testing requirement to material which is in storage, and already tested for HB_sAg by a less sensitive method than a third generation test, such as counterelectrophoresis, a second generation test.

It is the Commissioner's intention that all blood, plasma, or serum used as a biological product or used in manufacturing a biological product shall be tested for HB_sAg by the most sensitive test method available. However, the Commissioner is aware that there is valuable material in storage which will have been collected prior to the effective date of mandatory third generation testing, and may have been tested by a method of only second generation sensitivity. Such material is being stored in the frozen state and must therefore be thawed and the container entered to obtain a sample for testing by a third generation method of sensitivity for HB_sAg. This approach is impractical on a large scale. In view of the fact that consideration should be given to the most efficient yet safest use of the nation's blood, plasma, and serum supplies, the Commissioner has concluded that material which was tested by a method of second generation sensitivity and found to be nonreactive may be used as a biological product, or used in manufacturing a biological product, within 6 months after the effective date of these regulations. If such material is not used within the 6-month period, it shall be retested by a method of third generation sensitivity before being used as a biological product or before use in the manufacturing of a biological product. The final regulation is so amended in § 610.40(c).

7. Another comment regarding § 610.40 (a) (redesignated § 610.40(b) Procedures) suggested that the phrase "such test shall be performed on blood, plasma, or serum taken from the donor at the time of donation" should be deleted. Although no reason was given for suggesting the deletion, the Commissioner believes that the respondent misinterpreted the intent of the phrase to mean that HB_sAg testing must be performed on the day the sample is removed from the donor. In this regard, two other comments requested clarification of the same phrase.

It was the Commissioner's intention simply to identify the material on which the HB_sAg test is to be performed, and not to specify the time of the testing. To clarify the matter, § 610.40(b) has been revised to provide that the test for the presence of HB_sAg shall be performed on a sample of blood, plasma, or serum taken from the donor at the time of donation of the unit, and that HB_sAg testing itself need not be performed on the day of donation.

8. One comment noted that the proposal did not provide for off-premises testing for HB_sAg by the radioimmunoassay (RIA) method.

The Commissioner agrees that provisions for such testing should be addressed in the final regulation, because numerous small blood bank facilities throughout the country may find it difficult to budget the purchase of the necessary counting equipment for RIA testing. These same blood banks, however, may possess the required expertise to perform and read the RIA tests. The Commissioner is therefore amending § 610.40(b) to permit (1) blood collection facilities to perform the RIA test up to the point of counting at their own location, and then for their personnel to use the counting equipment of another facility or for the trained personnel of another facility to perform the actual counting operation, or (2) the complete RIA testing procedure to be performed by personnel at an establishment licensed to manufacture blood or blood derivatives under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or by a clinical laboratory which meets the standards of the Clinical Laboratories Improvement Act of 1967 (CLIA) (42 U.S.C. 263a), provided the establishment or the clinical laboratory is qualified to perform RIA testing for HB_sAg. Except for emergencies, the blood, plasma, or serum shall not be used as a biological product, or issued for use in manufacturing a biological product, until the HB_sAg testing is completed and the written results of the test are in the possession of the collecting facility.

Off-premises testing for HB_sAg by the RIA method may be interpreted to mean that such procedure is divided manufacturing by two establishments, thereby requiring that the name, address, and license number of each establishment must appear on the label of the product as specified in § 610.63 Divided manufacturing responsibility to be shown (21 CFR 610.63). The Commissioner does not consider off-premises testing to be divided manufacturing under § 610.63 when the requirements of § 610.40(e) are met. The purpose of permitting off-premises testing is to provide a means for all blood collection facilities, regardless of their size and economic situation, to give equal protection to all blood recipients against the danger of receiving blood which may contain the infectious hepatitis B virus. Accordingly, a new paragraph (e) Manufacturing responsibility is added to § 610.40 to specify the requirements that must be met by the collection facility and the off-premises testing facility in order not to be considered as operating in a manner subject to § 610.63.

9. One manufacturer of in vitro diagnostic reagents suggested that § 610.40 (a) be revised to permit HB_sAg testing of material intended for manufacture of in vitro diagnostic reagents to be performed on pooled material rather than requiring each unit to be tested separately.

The Commissioner rejects this suggestion, inasmuch as part of the intent of these regulations is to prevent unnecessary handling by individuals of HB_sAg positive material and to strictly limit entry of an excessive amount of HB_sAg positive material into interstate commerce. A pool of material may test nonreactive to HB_sAg, when in fact it contains an HB_sAg positive unit, because the positive unit was diluted by mixing with other nonreactive units beyond the sensitivity of the test method used to detect the presence of HB_sAg. The diluting of such a unit does not inhibit its potential for transmitting hepatitis and therefore, should not be handled unnecessarily by unsuspecting individuals or shipped in interstate commerce labeled as not containing hepatitis B virus. An additional reason for prohibiting the testing of pooled material, as opposed to testing single units, is that if a unit of material which contains HB_sAg is pooled with a unit or units of material that contain Anti-HB_s, the HB_sAg may be neutralized by the Anti-HB_s but the hepatitis B virus infectiousness may not be neutralized and its presence will not be detected by testing for HB_sAg.

10. Two comments regarding proposed § 610.40(b)(1) (redesignated § 610.40 (d)(1)) concerning restrictions on use suggested that a provision should be included to permit the utilization of HB_sAg reactive materials for authorized investigational purposes.

The Commissioner finds such provision is unnecessary in view of the provisions of § 607.21 Products under development (21 CFR 601.2) and § 312.1 Conditions for exemption of new drugs for investigational use (21 CFR 312.1), authorizing interstate shipments of investigational new drugs pursuant to a Notice of Claimed Investigational Exemption for a New Drug.

11. Three manufacturers commented that provision should be made in § 610.40 (b)(1) for those situations where inadvertent contamination of a large plasma pool for fractionation is discovered subsequent to pooling, due, for example, to a labeling or shipping error by the supplier of the plasma.

The Commissioner agrees that specific regulations should be developed to deal with this matter. However, he believes that such a situation is one that should be addressed in a separate proposal on which the public will have an opportunity to comment. Such a proposal will be published in the FEDERAL REGISTER in the near future.

12. Two comments on proposed § 610.40(b) (2) and (3) (redesignated § 610.40(d) (2) and (3)) concerning licensed and unlicensed in vitro diagnostic biological products voiced strong opposition to the use of HB_sAg positive material in in vitro diagnostic reagents.

Although the Commissioner stated, in the preamble to the Source Plasma (Human) proposal of July 17, 1974, his intention that the use of source HB_sAg positive blood, plasma, or serum be limited to the very few situations in which the final product can be prepared only from HB_sAg positive material, it appears that this was not made clear in the regulation itself. The Commissioner does does not believe that unrestricted use of HB_sAg positive source materials should be permitted in the manufacturing of such widely available in vitro diagnostic reagents as A, B, and D blood grouping sera. It is necessary, however, to provide for the use of HB_sAg positive source material in such cases as serum or plasma containing rare antibodies where the source is very limited, or for the positive control used in performing the HB_sAg test. Therefore, paragraph (d) (2) and (3) of § 610.40 prescribes in more detail the conditions under which known HB_sAg positive source material can be used in manufacturing an in vitro diagnositic biological product. The final regulation includes restrictions on the use of HB_sAg positive material to rare antisera or positive controls for use in HB_sAg testing, proper labeling of the source material as well as the final product, and notification to the Bureau of Biologics of such shipments.

13. One comment regarding § 610.40(b) (2) and (3) (redesignated § 610.40(d) (2) and (3)) requested that blanket approval be given by the Bureau of Biologics for shipments of HB_sAg positive material used in manufacturing positive controls for use in HB_sAg testing, because such shipments are made repeatedly to the same consignee(s) to maintain an adequate supply of controls for HB_sAg testing. Two comments expressed the view that it takes too long to obtain written clearance from the Bureau, and another comment inquired as to the criteria to be used by the Bureau in approving such shipments.

As discussed in paragraph 12 of this preamble, the Commissioner is amending the regulations to prescribe in more detail the conditions under which HB_sAg positive material may be used in manufacturing licensed and unlicensed in vitro diagnostic biological products. Such amendment removes the necessity of receiving prior written approval from the Bureau, because the criteria which the Bureau would have used in evaluating the request for approval of each shipment are now incorporated into the regulation itself. No prior written approval will therefore be required for each shipment, rather only notification at the time of shipment that a shipment has been made. An additional provision has been made in § 610.40(d) (2) to simplify notification to the Bureau of repetitive shipments of HB_sAg positive material to the same consignee. This provision requires periodic notification, every 6 months, for each consignee(s). The Commissioner is specifying the months of October and April as the reporting months to provide uniformity of reporting.

14. Two comments on § 610.40(b) (2) and (3) (redesignated § 610.40(d) (2) and (3)) suggested that all shipments of HB_sAg positive material should comply with the applicable regulations governing the shipment of etiologic agents.

The Commissioner endorses the principle that potentially infectious material should be required to be shipped in the safest manner possible to provide maximum protection to the public and the environment. However, he believes that adequate regulations already exist in that etiologic agents are required to be shipped in accordance with the provisions of 42 CFR 72.25 and therefore no further regulation is necessary under Title 21. Specific questions regarding the shipping of etiologic agents should be sent to the Biohazards Control Officer, Center for Disease Control, 1600 Clifton Rd., Atlanta, GA 30333; telephone 404–633–3311, extension 3883.

15. One comment regarding § 610.41 suggested that the prohibition of persons from serving as blood donors who have previously had an HB_sAg reactive test should not include those donors whose reactive test was demonstrated to be a "false positive" result.

The Commissioner agrees that a "false positive" test result should not be the basis for considering either a donor or a product HB_sAg reactive. In as much as all third generation test systems are now required to include the necessary reagents and directions for determining the specificity of the reactions obtained, thereby effectively eliminating the incidence of false positives, the Commissioner believes that no change of proposed § 610.41 is indicated.

16. Four comments regarding § 640.2 (f) is applicable to whole blood, suggested that provision be made for emergency situations. The comments suggested that in emergency situations a third generation test should not be required if medical judgment favors sustaining life even at the risk of possibly causing hepatitis.

The Commissioner recognizes that emergency situations may arise where the time necessary to complete a third generation test, 4 to 24 hours for the RIA test and 2 to 3 hours for the reversed passive hemagglutination test, is of greater risk to the patient's welfare than the risk of hepatitis. The Commissioner believes that in emergency situations, a second generation test should be permitted, such as the reversed passive latex agglutination test which can be completed in 5 minutes or the counterelectropheresis test which can be completed in 1 hour. The Commissioner also recognizes that there are rare dire emergencies where the patient's need for blood is so acute as to preclude any testing of the blood. The Commissioner believes that the use of hepatitis-untested blood in such dire emergencies should be permitted. Since products other than whole blood may need to be issued in emergency situations, the Commissioner has concluded that the provisions for emergency situations should appear in § 610.40(a) which is applicable to all blood products, rather than § 640.2(f) which is applicable only to whole blood. Therefor § 610.40(a) has been amended to permit HB_sAg testing of second generation sensitivity for blood and blood products in emergency situations and to permit the issuance of blood and blood products without any HB_sAg testing in dire emergency situations, provided that a test of third generation sensitivity is performed as soon as possible after issuance of the blood and blood product.

17. Six comments regarding § 660.4 *Potency test* expressed concern that the language of the proposal would prohibit the manufacture of HB_sAg testing reagents of second generation sensitivity, which could otherwise be used for emergency testing or for export to countries requesting the product.

It is not the intention of the Commissioner to prevent the manufacture of reagents other than those of third generation sensitivity. Indeed, as discussed in pargaraph 16 of this preamble, the Commissioner is cognizant of the need to allow for an MH_sAg test of second generation sensitivity to be used in emergency situations. The regulation as written does not require that all hepatitis testing reagents manufactured under license must be of third generation sensitivity. Reagents of first and second generation sensitivity which meet the applicable requirements of the Reference Hepatitis B Surface Antigen Panel will continue to be released by the Bureau of Biologics. The amended § 610.40 requires testing of blood by reagents of third generation sensitivity; it does not ban proper use of other HB_sAg reagents.

18. Five comments noted that there should be assurance of an adequate supply of HB_sAg testing reagents before an effective date is established for third generation testing.

In the preamble to the July 9, 1974 proposal, the Commissioner expressed his concern in this regard and stated that a survey of the availability of testing material would be made during the comment period following the proposal. The results of the informal survey indicate that an adequate supply of HB_sAg third generation testing reagents is available to meet all testing needs of this country. Presently, two manufacturers are licensed for the RIA method and one manufacturer is licensed for the RPHA method. It is expected that other manufacturers will be licensed in 1975.

Therefore, pursuant to provisions of the Public Health Service Act (sec. 351,

58 Stat. 702 as amended (42 U.S.C. 262) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 610, 640, and 660 of Subchapter F of Chapter I of Title 21, Code of Federal Regulations, are amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

1. In Part 610:

a. By revising § 610.13(a)(2) to read as follows:

§ 610.13 Purity.

* * * * *

(a) * * *

(2) *Test results; standard to be met.* The residual moisture and other volatile substances shall not exceed 1 percent except that, (i) they shall not exceed 1.5 percent for BCG Vaccine; (ii) they shall not exceed 2 percent for Measles Virus Vaccine, Live, Attenuated; Measles-Smallpox Vaccine, Live; Rubella Virus Vaccine, Live; and Antihemophilic Factor (Human); (iii) they shall not exceed 3 percent for Modified Plasma (Bovine); Thrombin; Fibrinogen; Streptokinase; Streptokinase-Streptodornase; and Anti-Influenza Virus Serum for the Hemagglutination Inhibition Test; and (iv) they shall not exceed 4.5 percent for Antibody to Hepatitis B Surface Antigen for the Reversed Passive Hemagglutination Test.

* * * * *

b. By revising § 610.40 to read as follows:

§ 610.40 Test for hepatitis B surface antigen.

(a) *Test sensitivity.* Each donation of blood, plasma, or serum to be used in preparing a biological product shall be tested for the presence of hepatitis B surface antigen by a method of sufficient sensitivity to detect all sera labeled A, (A), B, (B), and C in the Reference Hepatitis B Surface Antigen Panel distributed by the Bureau of Biologics; except that, in emergency situations, a test method of sufficient sensitivity to detect all sera labeled A, (A), and B in the Reference Hepatitis B Surface Antigen Panel may be used and, in dire emergency situations, blood and blood products may be issued without any HB_sAg testing, provided that a test otherwise required by this paragraph is performed as soon as possible after issuance of the blood and blood product.

(b) *Procedures.* Only Antibody to Hepatitis B Surface Antigen licensed under this subchapter shall be used in performing the test and the test method(s) used shall be that for which the antibody product is specifically designed to be effective as recommended by the manufacturer in the package insert. The sample of blood, plasma, or serum to be tested shall have been taken from the donor at the time of donation of that unit. The test need not be performed on the day of the withdrawal of the sample. If the radioimmunoassay method is used, it must be performed in one of the following ways:

(1) The complete test is performed at the collection facility.

(2) The test is performed at the collection facility up to the point of counting the radioactivity of the samples, which counting, thereafter, is performed at another facility by personnel from the collection facility or by personnel from the counting facility.

(3) The complete test is performed by the personnel at an establishment licensed to manufacture blood or blood derivatives under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or by a clinical laboratory which meets the standards of the Clinical Laboratories Improvement Act of 1967 (CLIA) (42 U.S.C. 263a), provided the establishment or the clinical laboratory is qualified to perform radioimmunoassay testing for the presence of hepatitis B surface antigen. Except for emergencies, blood, plasma or serum shall not be used as a biological product, or issued for use in manufacturing a biological product, until the hepatitis B surface antigen testing is completed and the written results are in the possession of the collection facility.

(c) *Materials in storage.* All blood, plasma, or serum in storage which has not been tested for the presence of the hepatitis B surface antigen shall be tested as required in paragraphs (a) and (b) of this section before use as a biological product, or before use in the manufacture of a biological product. All blood, plasma, or serum in storage which has been tested for the presence of the hepatitis B surface antigen by a method of second generation sensitivity may be used as a biological product or in manufacture of a biological product, provided it is used on or before March 15, 1976.

(d) *Restrictions on use.* (1) *Injectable biological products.* Blood, plasma, or serum that is reactive when tested for hepatitis B surface antigen shall not be used in manufacturing injectable biological products.

(2) *License in vitro diagnostic biological products.* Blood, plasma or serum that is reactive when tested for hepatitis B surface antigen may be used in manufacturing licensed in vitro diagnostic biological products: *Provided,* That (i) the final product cannot be prepared from blood, plasma, or serum that is nonreactive when tested for hepatitis B surface antigen, due either to the nature or to the scarcity of the final product; (ii) the label of the source blood, plasma, or serum conspicuously states that it is reactive when tested for hepatitis B surface antigen and may transmit viral hepatitis; (iii) the package label of the licensed in vitro diagnostic biological product prepared from such blood, plasma, or serum conspicuously states that the product was prepared from material that was reactive when tested for the hepatitis B surface antigen and may transmit viral hepatitis; (iv) at the time of shipment, the Director, Bureau of Biologics, Food and Drug Administration, is notified in writing of each shipment of source blood, plasma, or serum, signifying the kind and amount of source material shipped, the name and address of the consignee, the date of shipment, and the manner in which the source material was labeled. In the case of repetitive shipments of source material for use in manufacturing positive controls for hepatitis B surface antigen testing, the information prescribed in this paragraph (d)(2)(iv) shall be sent to the Director, Bureau of Biologics, on October 1 and April 1 of each year beginning October 1, 1975.

(3) *Unlicensed in vitro diagnostic biological products.* Blood, plasma, or serum that is reactive when tested for hepatitis B surface antigen may be used in manufacturing unlicensed in vitro diagnostic biological products including clinical chemistry control reagents, *Provided:* That (i) the final product cannot be prepared from blood, plasma, or serum that is nonreactive when tested for hepatitis B surface antigen, due either to the nature or to the scarcity of the final product; (ii) the label of the source blood, plasma, or serum conspicuously states that it is reactive when tested for hepatitis B surface antigen and may transmit viral hepatitis; (iii) the manufacturer of the source blood, plasma, or serum obtains written assurance from the manufacturer(s) of the final unlicensed product that package labels of all unlicensed products will conspicuously state that the product was prepared from blood, plasma or serum that was reactive when tested for the hepatitis B surface antigen and may transmit viral hepatitis, as required by § 328.10(a)(4) of this chapter; (iv) at the time of shipment, the Director, Bureau of Biologics, Food and Drug Administration, is notified in writing of each shipment of source blood, plasma, or serum, signifying the kind and amount of source material shipped, the name and address of the consignee, the date of shipment, and the manner in which such source material was labeled.

(e) *Manufacturing responsibility.* When the radioimmunoassay method for hepatitis B surface antigen testing is performed by personnel other than those of the facility collecting the blood, plasma, or serum, as provided in paragraph (b) of this section, it shall not be considered as divided manufacturing as described in § 610.63, provided the following conditions are met:

(1) The collecting facility has obtained a written agreement that the testing laboratory will permit authorized representatives of the Food and Drug Administration to inspect its testing procedures and facilities during reasonable business hours.

(2) The testing laboratory will participate in any proficiency testing programs undertaken by the Bureau of Biologics, Food and Drug Administration.

c. By revising § 610.41 to read as follows:

§ 610.41 History of hepatitis B surface antigen.

A person testing positive, or known to have previously tested positive, for hepa-

titis B surface antigen may not serve as a donor of human blood, plasma, or serum to be used in preparing any injectable biological product, except that a person known to have previously tested positive for hepatitis B surface antigen may serve as a source of antibody to hepatitis B surface antigen when such antibody is required for the manufacture of a licensed biological product, provided that the blood of such person meets the requirements of § 610.40.

d. By amending § 610.53 by deleting from the listing the item for "Hepatitis Associated Antibody (Anti-Australia Antigen)" and inserting in alphabetical order a new item, as follows:

§ 610.53 Dating periods for specific products.

Antibody to Hepatitis B Surface Antigen.	Six months (5° C, 6 months) except Iodinated (^{125}I) products. Iodinated (^{125}I) products, 45 days. § 610.51 does not apply.

e. By revising § 610.61(s) to read as follows:

§ 610.61 Package label.

(s) For injectable products prepared from human blood, plasma or serum, a statement that the product was prepared from blood that was nonreactive when tested for hepatitis B surface antigen. In lieu of inclusion on the package label, such information may be included in a circular enclosed with the package.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

2. In Part 640:

a. By revising § 640.2(f) to read as follows:

§ 640.2 General requirements.

(f) *Issue prior to determination of test results.* Notwithstanding the provisions of § 610.1 of this chapter, blood may be issued by the licensee on the request of a physician, hospital, or other medical facility before results of all tests prescribed in § 640.5 and the test for hepatitis B surface antigen prescribed in § 610.40(a) of this chapter have been completed, where such issue is essential to allow time for transportation to assure arrival of the blood by the time it is needed for transfusion of such blood: *Provided*, That (1) the blood is shipped directly to such physician or medical facility, (2) the records of the licensee contain a full explanation of the need for such issue, (3) the label on each container of such blood bears the information required by § 640.7(e), (4) the label does not bear results of tests other than those made on pilot samples of the blood to be shipped, taken at the time of its collection, and (5) the label does not bear the name or any other identification of the intended recipient.

b. By revising § 640.7(b) to read as follows:

§ 640.7 Labeling.

(b) *Serological test and test for hepatitis B surface antigen.* Indication of the method used for serological test for syphilis and the test for hepatitis B surface antigen, and the results.

c. By revising § 640.26(h) to read as follows:

§ 640.26 Labeling.

(h) Type of test for hepatitis B surface antigen used and the results.

d. By revising § 640.51(c)(7) to read as follows:

§ 640.51 General requirements.

(c) * * *

(7) Indication of test method for hepatitis B surface antigen used and the result.

e. By revising § 640.67 to read as follows:

§ 640.67 Test for hepatitis B surface antigen.

Each unit of Source Plasma (Human) shall be nonreactive to a test for the hepatitis B surface antigen as prescribed in §§ 610.40 and 610.41 of this chapter.

f. By revising § 640.69(e)(9) and (f)(1) to read as follows:

§ 640.69 General requirements.

(e) * * *

(9) The test for hepatitis B surface antigen used and the results.

(f) * * *

(1) The test for hepatitis B surface antigen pursuant to § 640.67.

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

Subpart A—Antibody to Hepatitis B Surface Antigen

3. In Part 660:

a. By revising the heading for Subpart A to read as set out above.

b. By revising § 660.1 to read as follows:

§ 660.1 Antibody to Hepatitis B Surface Antigen.

(a) *Proper name and definition.* The proper name of this product shall be Antibody to Hepatitis B Surface Antigen. The product is defined as a preparation of serum containing antibody to hepatitis B surface antigen.

(b) *Source.* The source of this product shall be plasma or blood, obtained aseptically from animals immunized with hepatitis B surface antigen, which have met the applicable requirements of § 600.11 of this chapter, or from human donor whose blood is positive for hepatitis B surface antigen.

c. By revising paragraphs (e) and (f) of § 660.2 to read as follows:

§ 660.2 General requirements.

(e) *Date of manufacture.* The date of manufacture of Antibody to Hepatitis B surface Antigen that has been iodinated with radioactive Iodine (^{125}I) shall be the day of labeling the antibody with the radionuclide.

(f) *Samples; protocols; official release*—(1) *Antibody to Hepatitis B Surface Antigen.* Except as provided in this paragraph, the following material for each filling of the product shall be submitted to the Director, Bureau of Biologics:

(i) A sample of each filling packaged as for distribution, including all ancillary reagents and materials.

(ii) A protocol which consists of a summary of the history of manufacture of each filling, including all results of each test for which test results are requested by the Director, Bureau of Biologics.

(iii) No filling of the product shall be issued by the manufacturer until notification of official release of the filling is received from the Director, Bureau of Biologics.

(2) *Antibody to Hepatitis B Surface Antigen iodinated with ^{125}I.* Antibody to Hepatitis B Surface Antigen that has been iodinated with radioactive Iodine (^{125}I) may be released by the manufacturer pursuant to the requirements of § 610.1 of this chapter without obtaining an official release from the Director, Bureau of Biologics provided:

(i) The manufacturer submits to the Bureau of Biologics a protocol of each master lot along with one sample of the lot, such material to be postmarked no more than 1 day following the manufacturer's release date.

(ii) At least two complete kits of each released lot are retained as retention samples for no less than 90 days from the date of manufacture.

d. By revising § 660.3 to read as follows:

§ 660.3 Reference panel.

A Reference Hepatitis B Surface Antigen Panel shall be obtained from the Bureau of Biologics and shall be used for determining the potency and specificity of Antibody to Hepatitis B Surface Antigen.

e. By revising § 660.4 to read as follows:

§ 660.4 Potency test.

To be satisfactory for release, each filling of Antibody to Hepatitis B Surface Antigen shall be tested against the Reference Hepatitis B Surface Antigen Panel and shall be sufficiently potent to detect the antigen in the appropriate sera of the reference panel by all test methods recommended by the manufacturer in the package insert.

f. By revising § 660.5 to read as follows:

§ 660.5 Specificity.

Each filling of the product shall be specific for antibody to hepatitis B surface antigen, as determined by specificity tests found acceptable by the Director, Bureau of Biologics.

Effective date. The effective date of this regulation shall be September 15, 1975, except for labeling revisions necessitated by changing all references to "hepatitis associated (Australia) antigen" to read "hepatitis B surface antigen," and the proper name of "Hepatitis Associated Antibody (Anti-Australia Antigen)" to read "Antibody to Hepatitis B Surface Antigen," which revisions shall be effective September 15, 1976.

(Sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262))

Dated: July 8, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-18219 Filed 7-14-75;8:45 am]

Title 23—Highways

CHAPTER I—FEDERAL HIGHWAY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

SUBCHAPTER B—PAYMENT PROCEDURES

PART 140—REIMBURSEMENT

Reimbursement for Railroad Work

The Federal Highway Administration hereby amends Subpart I of Part 140 to provide for the reimbursement to railroad companies for construction cost and for the cost of materials stockpiled at the construction site, all of which are incurred after an appropriate State-Railroad Agreement has been approved by the FHWA. This amendment also adds, for calendar year 1975, the rates for labor surcharges to Appendix A to Subpart I. In addition, this amendment corrects an error contained in the rate table of payroll taxes for supplemental annuities set forth in Appendix A which was published in the FEDERAL REGISTER on April 9, 1975 (40 FR 16059).

1. In § 140.922 paragraphs (a), (b), and (c) are redesignated (b), (c) and (d) respectively and a new paragraph (a) is 646.218 below.

§ 140.922 Billings.

(a) After the executed State-Railroad Agreement has been approved by FHWA, the company may be reimbursed on progress billings of incurred costs. Costs for materials stockpiled at the project site or specifically purchased and delivered to the company for use on the project may be reimbursed on progress billings following approval of the executed State-Railroad Agreement or the written agreement under 23 CFR 646.218(c).

* * * * *

2. Appendix A to 23 CFR, Part 140, Subpart I, Rates for Labor Surcharges, is amended to delete the figure "-75" from the last line and to add a final entry to the chart setting forth rates and limitations to read as follows:

Calendar year	Monthly limitation		Full legal rate		Combined rate less ¼ percent
	Retirement	Unemployment insurance	Retirement	Unemployment insurance	
		Percent	*Percent*		
1975	1,175	400	15.35	4	19.10

3. Appendix A is corrected to delete the phrase "July 1, 1975 until changed .... 8½" from the rate table of payroll taxes for supplemental annuities and inserting in lieu thereof the phrase "Jan. 1, 1975 until changed .... 8½."

This amendment will take effect on July 10, 1975.

Issued on July 7, 1975.

J. R. COUPAL, Jr.,
Acting Federal Highway Administrator.

[FR Doc.75-18294 Filed 7-14-75;8:45 am]

SUBCHAPTER G—ENGINEERING AND TRAFFIC OPERATIONS

PART 646—RAILROADS

Railroad-Highway Projects

The Federal Highway Administration hereby revises Subpart B of Part 646 to provide that cost incurred by a railroad company for materials stockpiled at the construction site of a railroad-highway project may be reimbursed on progress billings following approval by the FHWA of an appropriate State-railroad agreement. A typographical error is also corrected on § 646.220(b)(1).

1. Section 646.216(e)(2)(ii) is revised to read as follows:

§ 646.216 General procedures.

* * * * *

(e) * * *

(2) * * *

(ii) A proposed agreement between the State and railroad must be found satisfactory by FHWA. Before Federal funds may be used to reimburse the State for railroad costs the executed agreement must be approved by FHWA. However, cost for materials stockpiled at the project site or specifically purchased and delivered to the company for use on the project may be reimbursed on progress billings prior to the approval of the executed State-Railroad Agreement in accordance with 23 CFR 140.922(a) and section 646.218 below.

§ 646.220 [Amended]

2. The second line of § 646.220(b)(2) is corrected to insert "646.206(a)(3)" in lieu of "646.206(a)(3)."

This revision will take effect on July 10, 1975.

Issued on July 7, 1975.

J. R. COUPAL, Jr.,
Acting Federal Highway Administrator.

[FR Doc.75-18295 Filed 7-14-75;8:45 am]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER C—AIR PROGRAMS

[FRL 387-2]

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Approval of Compliance Schedules: California

On March 27, 1975, there was published in the FEDERAL REGISTER (40 FR 13520) a notice of proposed rulemaking which proposed to approve 27 compliance schedules submitted by the Governor of California through his designee, pursuant to 40 CFR 51.6, as revisions to the compliance schedule portion of the California plan for the implementation of the National Ambient Air Quality Standards. The only comments received by EPA from the public on the proposed rulemaking concerned revisions to schedules which have not been officially submitted to EPA by the State of California. The comments therefore do not affect this rulemaking.

Each revision establishes a new date by which the individual air pollution source must comply with the applicable air pollution control regulations specified in the table below. This date is indicated in the table under the heading "Final Compliance Date". In some cases the schedule includes incremental steps towards compliance with the specified regulations. While the table below does not include these interim dates, the actual compliance schedule does. The increments of progress, as well as the final compliance date, are legally enforceable by the Administrator pursuant to Section 113 of the Clean Air Act, as amended (42 USC § 1857c-8).

The heading "Effective Date" in the table below refers to the date the compliance schedule becomes effective for purposes of federal enforcement. The entry "Immediately" under that heading indicates that the schedule will be federally-enforceable when the final promulgation of the schedule becomes effective.

A copy of the complete California State Implementation Plan, including these schedules, is available for public inspection at the addresses listed below:

California Air Resources Board, 1704 11th Street, Sacramento CA 95814.

Environmental Protection Agency, Region IX, Enforcement Division, 100 California Street, San Francisco CA 94111.

Environmental Protection Agency, Room 3202, Waterside Mall, 401 M Street SW, Washington, D.C. 20460.

An evaluation report setting forth EPA's position on each of the schedules is also available at the office of EPA, Region IX.

The Administrator has determined that the 27 proposed compliance schedules are consistent with the requirements