Acquisition & Assistance Policy Directive (AAPD)

From the Director, Office of Acquisition & Assistance Issued: February 9, 2007

AAPD 07-01

Procurement of Anti-Retrovirals for HIV/AIDS Programs

Subject Category: ACQUISITION MANAGEMENT/ASSISTANCE/ POPULATION, HEALTH & NUTRTION

Type: PROCEDURE

See also Amendment 1, issued December 16, 2008

AAPDs provide information of significance to all agency personnel and partners involved in the Acquisition and Assistance process. Information includes (but is not limited to): advance notification of changes in acquisition or assistance regulations; reminders; procedures; and general information. Also, AAPDs may be used to implement new requirements on short-notice, pending formal amendment of acquisition or assistance regulations.

AAPDs are EFFECTIVE AS OF THE ISSUED DATE unless otherwise noted in the guidance below; the directives remain in effect until this office issues a notice of cancellation.

This AAPD: ☒ Is New ☐ Replaces/ ☐ Amends CIB/AAPD No:

Applicable to:	Precedes change to:
☒ Existing awards; ☐ Modification required	☐ AIDAR Part(s) Appendix
☐ No later than	☒ USAID Automated Directives System (ADS) Chapters 302 and 303
☐ As noted in guidance below	☐ Code of Federal Regulations
☒ RFPs/RFAs issued on or after the effective date of this AAPD; all other Pending Awards, i.e., 8(a), sole source, IQC	☐ Other
☐ Other or N/A	☒ No change to regulations

(signature on file)

PURPOSE:

The purpose of this AAPD is to inform USAID's acquisition and assistance workforce and its contractor and recipient community working in HIV/AIDS programs that certain approved Anti-Retroviral pharmaceuticals (Approved ARVs) may be procured without regard to:

- Source, orgin, and nationality restrictions contained in USAID Regulation 28 (http://www.access.gpo.gov/nara/cfr/waisidx_06/22cfr228_06.html; and
- "Restricted commodity" approval requirements contained in ADS 312.5.3c (http://www.usaid.gov/policy/ads/300/312.pdf).

Actions required:

- Funding for the procurement of USAID-approved ARVs must be obligated by September 30, 2008 (Guidance: Para E); and
- Advance approvals for the procurement of Approved ARVs must state that such procurements must be made in accordance with the terms of this AAPD and cite the number assigned to this AAPD (Guidance: Subpara F.2.).

BACKGROUND: Under ADS 312, USAID financing of pharmaceuticals is generally restricted to those that have received the U.S. Food and Drug Administration's (FDA) full approval. In the case of ARVs, two other categories of ARVs are also eligible: 1) FDA Tentatively-Approved ARVs; and 2) USAID-Approved ARVs:

1. FDA Tentatively-Approved ARVs. On January 26, 2005, Ambassador Randall L. Tobias, then the U.S. Global AIDS Coordinator, approved (under HIV/AIDS notwithstanding authority) procurement of ARVs "tentatively approved" by FDA under the FDA's program of expedited review. "Tentatively approved" means that while existing patents or exclusivity agreements prohibit the sale of the ARV in the United States, the ARV meets the same FDA standards for safety, efficacy, and manufacturing quality as do drugs sold in the United States. At present, several ARVs, including several drugs commonly recommended as part of first-line therapy and some combination preparations, have been tentatively-approved by the FDA. These tentatively-approved ARVs are eligible for USAID procurement for any agency HIV/AIDS programs, not just those funded with Global HIV/AIDS Initiative (GHAI) funds. Ambassador Tobias' January 2005 approval permits FDA tentatively-approved ARVs to be procured notwithstanding Sections 604 and 606 of the Foreign Assistance Act, as amended. The Office of the Global AIDS Coordinator has been consulted and concurs on this provision.

2. USAID-Approved ARVs. On April 29, 2005, then Administrator Natsios approved a "Blanket ARV Waiver" of source, origin, and nationality requirements for the procurement of ARVs of innovator companies manufactured in specific non-U.S. sites. (An innovator company is the brand-name company that has U.S. patent protection for an ARV. This patent protection gives the

company the sole right to sell the drug for a certain period of time in the United States.) The Action Memorandum approved by Administrator Natsios is at Attachment 1. It contains the procedure for AA/GH approval of additional ARVs. AA/GH has delegated that approval authority to GH/OHA.

USAID Contracting Officers (COs) and Agreement Officers (AOs) have authority to grant advance approvals and consent to expedite the procurements of eligible ARVs.

GUIDANCE:

A. Approved ARVs. USAID and USAID's contractors and recipients may procure ARVs for USAID HIV/AIDS programs that have:

- Full approval by FDA;
- Tentative approval by FDA; or
- USAID Approval under the Blanket ARV Source Waiver.

B. "USAID Consolidated List of Approved ARVs". All ARVs approved under paragraph A will be placed on the "USAID Consolidated List of Approved ARVs" that GH/OHA/SCMS will maintain at http://www.usaid.gov/our_work/global_health/aids/TechAreas/treatment/scms.html, and GH/OHA/SCMS will inform USAID Missions and Offices as additional ARVs are approved by FDA or USAID and are added to the Consolidated List.

C. New FDA-Approved ARVs. ARVs are eligible for procurement immediately upon full or tentative approval by the FDA. Updates of FDA-approved ARVs may be found at http://www.fda.gov/oia/pepfar.htm.

D. New USAID-Approved ARVs. GH/OHA has the authority to approve new ARVs under the Blanket ARV Waiver, which are eligible for USAID procurement upon written approval by the GH/OHA director or acting director. Manufacturers or others wishing to have an ARV approved by USAID should contact Carl Hawkins, GH/OHS/SCMS, chawkins@usaid.gov, 202-712-4539.

E. Expiration of Authority for USAID-Approved ARVs. Funding for the procurement of USAID-approved ARVs on the List must be obligated prior to September 30, 2008, the expiration date of the Blanket ARV Source Waiver. There is no expiration date for the procurement of FDA-approved ARVs.

F. Office of Acquisition and Assistance (OAA) and CO and AO Approvals.

1. OAA "restricted commodity" approval of pharmaceuticals, under ADS 312.5.3c, is not required for Approved ARVs.

2. Under contracts and agreements awarded prior to the issuance of this AAPD, COs and AOs may give advance approval for procurement of Approved ARVs under the (a) the AIDAR provision 752.225-70, "Source, Origin and Nationality Requirements",

(b) source/origin or "restricted commodity" provisions of the Mandatory Standard Provisions for U.S., Nongovernmental Recipients "USAID Eligibility Rules for Goods and Services", or (c) other similar assistance agreement provisions. For contracts and agreements awarded after the issuance of this AAPD, COs and AOs may include language in the schedule or elsewhere that indicates that, under the authority of the source waiver, advance CO/AO approval is granted for procurement of Approved ARVs under the above AIDAR clause or similar assistance agreement provisions. This language must state that such procurement must be made in accordance with terms of this AAPD and cite the number assigned to this AAPD.

3. COs may give advance consent to subcontracts for procurement of Approved ARVs in amounts in excess of the simplified acquisition threshold under FAR clause 52.244-2, Subcontracts.

4. Once a contractor requests CO consent to a subcontract for the procurement of Approved ARVs that is in excess of the simplified acquisition threshold, the CO may consent to the current and any future subcontracts that are solely for the procurement of any of the Approved ARVs.

G. This AAPD supersedes the July 8, 2005 USAID General Notice with the same title.

POINT OF CONTACT: Any questions concerning this AAPD may be directed to Carl Hawkins, GH/OHA/SCMS, chawkins@usaid.gov, 202-712-4539.

ATTACHMENTS:

1. Action Memorandum, "Source and Origin Waiver for the Procurement of Anti-Retrovirals for use in HIV/AIDS Programs", dated April 29, 2005.

2. Sample Letter to Contractors and Recipients.

ES200501520
File: HLS

Attachment 1

U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

April 20, 2005

ACTION MEMORANDUM

TO: The Administrator

FROM: AA/GH, Kent Hill /s/

SUBJECT: Source and Origin Waiver for the Procurement of Anti-retrovirals for use in HIV/AIDS programs and Delegation of Authority

ISSUES FOR DECISION

Whether to (1) approve a source and origin waiver from Geographic Code 000 (United States) to Geographic Code 935 countries (any country or area outside the United States excluding foreign policy restricted countries) for the procurement of the anti-retroviral drugs ("ARVs") listed on Attachment 1; and (2) delegate authority to AA/GH to amend the approved list when necessary to include additional ARVs when they meet the criteria specified in Attachment 2.

ESSENTIAL FACTORS

I. Procurement of ARVs

Ambassador Tobias has indicated that he will invoke notwithstanding authority for the procurement of non-U.S. manufactured ARVs that receive FDA tentative approval. The invocation of notwithstanding authority does not apply to ARV drugs that have not been approved or tentatively approved by the FDA, e.g. brand drugs produced in Europe that do not have FDA approval. Therefore, this source and origin waiver is necessary to procure essential drugs that have not been tentatively approved by the FDA and accelerate the mobilization of these drugs to fulfill the President's Emergency Plan for AIDS Relief (PEPFAR) objective of increasing the number of HIV/AIDS infected individuals receiving treatment.

A. ARVs receiving HHS/FDA Tentative Approval -- Notwithstanding Invoked

The FDA has provided tentative approval for a blister pack of the ARV AZT/3TC and NVP, manufactured by the South African company Aspen Pharmacare. Following that approval, Ambassador Tobias notified USAID that he would invoke notwithstanding authority for all FDA tentatively approved ARV drugs. (See Attachment 3, Letter from Ambassador Tobias to Administrator Natsios dated January 26, 2005.) That authority applies to the Aspen product. Therefore, there is no need for a waiver to purchase the Aspen product, and any ARV drugs approved through that process. The Aspen Pharmacare ARV is listed on Attachment 1.

Following the announcement of any drugs with similar approvals, Ambassador Tobias has indicated that notwithstanding authority will be invoked so PEPFAR funds can be used for purchase immediately following approval. When such action has been taken, Attachment 1 will be updated.

B. Waiver Process for Procurement of Other Non-U.S. Manufactured ARVs

The applicable statute and regulations covering USAID's source and origin requirements and pharmaceutical requirements appear in Section 604(a) of the Foreign Assistance Act of 1961, ADS Section 312.5.3c(2) and in 22 CFR 228. Exceptions to the general rule that USAID-financed pharmaceuticals must be of U.S. source and origin will be considered if:

1. it is necessary to promote efficiency in the use of US foreign assistance resources, including to avoid impairment of foreign assistance objectives (Subpart F of 22 CFR 228);

2. the pharmaceutical product is essential to the activity (ADS E312.5.3c);

3. information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the FDA or other U.S. controlling authority(ADS E312.5.3c); and

4. U.S. patent laws must be honored (ADS section E312.5.3c(3)).

1. Necessary to avoid impairment of foreign assistance objectives

This waiver is necessary to promote efficiency in the use of U.S. foreign assistance resources in that it will allow for the purchase of safe, quality ARVs of non-U.S. source and origin that are critical to the life-extending initiatives of Agency HIV/AIDS programs worldwide. This waiver, its list of approved ARVs (Attachment 1), and defined procedure for the addition of other approved ARVs (Attachment 2), will expand the Agency's ability to respond to HIV/AIDS program initiatives more rapidly while protecting our interests and ensuring compliance with applicable laws and regulations.

Without access to high quality, low cost ARVs that are approved for use in the countries in which USAID works, missions will be unable to get ARVs to those who need them and unable to reach the targets in support of the PEPFAR treatment goal to treat 2 million people with ARV therapy.

In many of the countries in which USAID is implementing HIV/AIDS programs and activities, critically required ARVs manufactured in the United States are not available as they are not included on the Country Pharmaceutical List, a listing of drugs eligible for sale in the country, or, if they are available, the cost is significantly higher. In addition, in some instances, ARVs produced by U.S. corporations are manufactured at company facilities in Europe or elsewhere, and from there imported to the concerned country. As you will note from Attachment 1, most of the ARVs concerned by this waiver are manufactured in foreign plants of U.S. pharmaceutical manufacturers and thus the intent of the goals and the purposes of the aforementioned source and origin requirements are largely met.

Many of the poor HIV positive patients served through USAID programs who need to be on ARVs will, in all likelihood, die in the near future without these drugs. Therefore, approval of this source and origin waiver is necessary to promote efficiency in the use of U.S. foreign assistance resources and to avoid impairment of foreign assistance objectives.

2. The ARVs are essential for the activity

The ARVs that will be purchased are essential for the activity. The HIV/AIDS programs require the medications listed in Attachment 1 to provide appropriate treatment and meet the program and PEPFAR goal of increasing the number of HIV infected individuals receiving treatment.

3. Safety, efficacy and quality

For the ARVs listed on Attachment 1, information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the FDA . Moreover, if the FDA-approved product is made at a plant outside of the United States, the plant has been approved and regulated by the FDA or another stringent regulatory authority.

The USG representatives in country are satisfied that the implementing organizations understand the importance of protecting these products during storage, handling and distribution from deterioration, damage and loss, and the products correspond to the nationally-approved standard treatment guidelines in the country in which they will be used.

4. U.S. Patent Laws

The ARVs listed on Attachment 1 do not infringe U.S. patent laws.

C. Decision Protocol

All of the ARVs that are to be procured will be either of U.S. source and origin or from Geographic Code 935 countries. The following decision protocol will be used to determine the specific supplier for each ARV:

1. If the product is manufactured in the U.S. only, the product will be procured from geographic code 000 source and origin;

2. If the product is manufactured in the United States only, but is distributed through an off-shore regional distributor, the product will be procured from code 000 origin and code 935 source;

3. If the product is manufactured in the United States and another country, the product will be procured from the source that meets the registration requirements of the recipient country provided information from a stringent regulatory authority is on file to document the safety, efficacy and quality of the products, and that the products do not infringe existing U.S. patent laws;

4. If the product is not manufactured in the United States, the product will be procured from the lowest cost, most programmatically appropriate supplier with code 935 source and origin that meets the registration requirements of the recipient country, provided information from a stringent regulatory authority is on file to document the safety, efficacy and quality of the products, and that the products do not infringe existing U.S. patent laws.

This protocol gives priority to the purchase of ARVs of U.S. source and origin whenever possible, but permits purchase of essential ARVs offshore, if necessary, in order to avoid inefficient use of foreign aid resources and impairment of foreign assistance objectives.

Your approval will be in effect throughout the period of the President's Emergency Plan for AIDs Relief (PEPFAR), ending September 30, 2008, and will apply to all sources of funds including prior year funds. Records will be kept on all uses of the waiver authorities. A review will be held at the end of the first year, and each subsequent year of the life of the waiver, to determine the adequacy of the waiver authorities and their continuing need.

II. Delegation of Authority to AA/GH to Amend Attachment 1

Attachment 2 provides criteria for adding ARVs to the approved list of ARVs on Attachment 1. To facilitate the process for amending this list, we ask that the Administrator delegate the authority to the AA/GH to amend Attachment 1 when necessary to include additional ARVs when they meet the specified criteria.

AUTHORITY

Although the Administrator has delegated to the AA/GH the authority to waive source, origin, and nationality requirements for the procurement of goods and services per ADS 103.3.8.3, due to the political sensitivity of this waiver, we are seeking the Administrator's approval.

CONSULTATIONS

The Bureau for Global Health has consulted with the State Global AIDS Coordinator's Office concerning the text of this waiver.

In addition, the Office of Legislative and Public Affairs has consulted with appropriate committees of Congress and have their concurrence regarding the necessity for this source and origin waiver.

RECOMMENDATIONS

1. That based on the findings above, you authorize the procurement of the ARVs listed on Attachment 1 from Geographic Code 935 countries (any country or area outside the United States excluding foreign policy restricted countries).

Approve Andrew S. Natsios

Disapprove _____

Date 29 April 2005

2. That you delegate authority to AA/GH to amend Attachment 1 when necessary to include additional ARVs when they meet the criteria specified in Attachment 2.

Approve Andrew S. Natsios

Disapprove _____

Date 29 April 2005

Attachments:

1. Approved list of ARVs dated April 7, 2005
2. Procedure for Addition of ARVs to Approved List dated April 7, 2005
3. Letter from Ambassador Tobias to Administrator Andrew Natsios dated January 26, 2005

Attachment 1: Approved list of ARVs dated April 7, 2005

Generic Name	Strength	Dosage form	Supplier	Manufacturing site	
Nevirapine	200mg	Tablet	Boehringer Ingelheim	Boehringer Ingelheim Pharma GmbH & Co., KG, Ingelheim	Germany
Nevirapine	50mg/5ml	Susp, Oral	Boehringer Ingelheim	Boehringer Ingelheim Pharma GmbH & Co., KG, Ingelheim	Germany
Didanosine	25 mg	Tablet	Bristol Myers Squib	Meymac	France
Didanosine	50 mg	Tablet	Bristol Myers Squib	Meymac	France
Didanosine	100 mg	Tablet	Bristol Myers Squib	Meymac	France
Didanosine	200mg	Tablet	Bristol Myers Squib	Meymac	France
Didanosine	400mg	Tablet	Bristol Myers Squib	Meymac	France
Didanosine	125mg, 200mg, 250mg	Enteric Capsules	Bristol Myers Squib	Meymac	France
Stavudine	15mg	Capsule	Bristol Myers Squibb	Meymac	France
Stavudine	20mg	Capsules	Bristol-Myers Squibb	Meymac	France
Stavudine	30mg	Capsule	Bristol Myers Squibb	Meymac	France
Stavudine	40mg	Capsule	Bristol Myers Squibb	Meymac	France
Stavudine	1mg/ml	Powder or Oral Susp	Bristol Myers Squibb	Meymac Evansville, IN	France USA
Stavudine	5mg/ml	Susp, Oral	Bristol Myers Squibb	Meymac	France
Abacavir	300 mg	Tablet	GlaxoSmithKline	GSK, Ware, Hertfordshire	UK
Abacavir	20mg/ml	Syrup	GlaxoSmithKline	GSK, Mississauga	Canada
Lamivudine	150mg	Tablet	GlaxoSmithKline	GSK, Ware, Hertfordshire	UK
Lamivudine+ Zidovudine	150mg + 300mg	Tablet	GlaxoSmithKline	GSK, Ware, Hertfordshire	UK
Lamivudine	10mg/ml	Susp, Oral	GlaxoSmithKline	GSK, Mississauga	Canada
Lamivudine	50mg/5ml	Syrup	GlaxoSmithKline	GSK, Mississauga	Canada
Zidovudine	300mg	Tablet	GlaxoSmithKline	GSK, Ware, Hertfordshire	UK
Zidovudine	250mg	Tablets	GlaxoSmithKline	GSK; Ware; Hertfordshire	UK
Zidovudine	100mgs	Tablets	GlaxoSmithKline	GSK; Ware; Hertfordshire	UK
Zidovudine	50mg/5ml	Syrup	GlaxoSmithKline	GSK, Mississauga	Canada
Zidovudine	300mg	Tablets	GlaxoSmithKline	GSK, Aranda	Spain
Efavirenz	50 mg	Capsule	Merck	Haarlem	The Netherlands
Efavirenz	200mg	Capsule	Merck	Haarlem	The Netherlands
Efavirenz	600mg	Tablet	Merck	Haarlem	The Netherlands
Efavirenz	30mg/ml	Syrup	Merck	Haarlem	The Netherlands
Indinavir Sulfate	400mg	Capsule	Merck	Haarlem	The Netherlands
Saquinavir/ Mesylate	200mg	Hard Gel Capsule	Roche	Basel	Switzerland

Saqinavir/Vesylate	200mg	Soft Gel Capsule	Roche	Basel	Switzerland
Tenofovir	300mg	Tablets	Gilead	Patheon Inc, Mississauga, Ontorio	Canada
Lopinavir/Ritonavir	133mg/33mg	Capsule	Abbott	Rp Scherer, St Petersburg	USA
Lopinavir/Ritonavir	80mg/20mg/ml	Solution	Abbott	Abbott Labs Ltd, Queensborough Rp Scherer, St Petersburg	UK USA
Ritonavir	100mg	Capsule	Abbott	Rp Scherer St Petersburg Rp Scherer, Benheim Packaging, Queensborough	USA France UK
Norvir Sol	80mg/ml	Solution	Abbott	Abbott Labs Limited Queensborough	UK
Nelfinavir	250 mg	Tablet	Roche	Madrid Basel	Spain Switzerland
Didanosine (ddI)	2gm,20mg/ml	Oral solution	Bristol-Myers Squibb	France or USA	France
Nelfinavir(NFV)	50mg/g	Oral powder	Hoffman-La Roche	Switzerland	Switzerland
Nevirapine (NVP)	10mg/ml	Oral solution	Boeringer Ingelheim	USA	Greece
Zidovudine (AZT)	10mg/ml	Oral solution	GlaxoSmithKline	Canada	Canada
Aspen Lamzid and Nevirapine Combo Pack Lamivudine/ zidovudine fixed dose combination tablets	C 150mg / AZT 300 mg + NVP 200mg	Tablets	Aspen Pharmacare	Aspen Pharmacare	South Africa

Attachment 2: Procedure for Addition of ARVs to Approved List dated April 7, 2005

In order to add an Anti -Retroviral drug to the Approved List, a request must be submitted to the AA/GH through the Director of GH/OHA that includes the following:

1. Generic name of the ARV, strength, dosage form, supplier name and manufacturing site(s);

2. Whether the ARV, producer and facility have been approved and are regulated by the FDA or some other stringent regulatory authority[1]. If the latter, provide details.

3. Justification for adding the proposed ARV .

4. Whether the FDA has tentatively approved the ARV according to the expedited process .

Once GH/OHA has approved a new ARV, GH/OHA will make a recommendation to the AA/GH to add the ARV to the list in Attachment 1. GH/OHA will submit a copy of the revised list to M/OAA to be added to the AAPD for this waiver to update procurement policy.

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[1] A stringent regulatory authority is a drug regulatory body that closely resembles FDA in standards utilized in its operations. Currently, countries that participate in the International Conference on Harmonization (ICH) are considered as stringent regulatory authorities. The ICH regulatory bodies include: the U.S. FDA; the Japanese Ministry of Health, Labor, and Welfare; the European Agency for the Evaluation of Medicinal Products (EMEA) centralized procedure; and the European Free Trade Area (represented by the Swiss Medic). The Canadian drug regulatory authority, the Therapeutic Products Directorate, Health Canada, is an observer to the ICH and is also considered a stringent regulatory authority. Other countries may be considered having a stringent regulatory body if they have implemented ICH guidelines and resemble the U.S. FDA in operation, but would be considered on a case-by-case basis.

ES200500751

3 copies please. Thanks

United States Department of State
Washington, D.C. 20520
www.state.gov

January 26, 2005

The Honorable Andrew S. Natsios
Administrator
U.S. Agency for International Development
Washington, D.C.

VIA FACSIMILE: (202) 216-3455

USAID
SECRETARIAT
2005 JAN 26 P 4:33

Dear Administrator Natsios:

An historic aspect of President Bush's Emergency Plan for AIDS Relief, endorsed by the U.S. Congress, is to support access to life-saving anti-retroviral drug therapy for those who are suffering from HIV/AIDS around the world. I have publicly stated that I will use the resources of the Emergency Plan to purchase the lowest-cost drugs, regardless of origin, when demonstrated to be safe, effective and of high quality.

In May 2004, Secretary of Health and Human Services Tommy Thompson announced an expedited process at the Food and Drug Administration within the Department of Health and Human Services (HHS/FDA) for reviewing certain potential HIV/AIDS drug therapies for the President's Emergency Plan. This expedited process is available to manufacturers of brand-name and generic drugs in any country of the world. Most important, the process maintains the normal rigorous HHS/FDA safety, efficacy, and quality standards. In the case of the expedited review of drug therapies for which a firm other than the applicant manufacturer holds the U.S. patent rights, HHS/FDA issues what it refers to as a "tentative approval" after the product meets the agency's normal safety, efficacy, and quality standards.

In May 2004, when Secretary Thompson announced the expedited process, I made known that the Office of the U.S. Global AIDS Coordinator will recognize HHS/FDA tentative approval as evidence of the safety, efficacy, and quality of HIV/AIDS drug therapies and, in that regard,

consider such tentatively approved medicines eligible for procurement under the President's Emergency Plan for AIDS Relief, consistent with international patent regimes and agreements. Where certain U.S. foreign assistance restrictions such as Sections 604 and 606 of the Foreign Assistance Act of 1961, as amended, would impede the provision of tentatively approved anti-retroviral drugs to developing countries, the Office of the U.S. Global AIDS Coordinator intends to rely upon the notwithstanding authority available under the Foreign Operations, Export Financing, and Related Programs Appropriations Acts to provide approved drug therapies as necessary.

The timely provision of quality, life-saving drug therapies to millions of men, women and children who are suffering from HIV/AIDS will be an important component of the success of the President's Emergency Plan for AIDS Relief. I appreciate your support in expanding treatment under the Plan as, together, we work to ensure that the generosity and compassion of the American people will turn the tide against HIV/AIDS.

Sincerely,

Ambassador Randall L. Tobias
U.S. Global AIDS Coordinator

Attachment 2

Sample Letter to Contractors and Recipients

From: Contracting Officer or Agreement Officer as appropriate

Subject: Procurement of Antiretrovirals (ARVs)

The purpose of this letter is to provide USAID approval for "Approved ARVs" under Acquisition and Assistance Policy Directive (AAPD) 07-__ [*insert number assigned*], Procurement of Anti-Retrovirals for HIV/AIDS Programs. The AAPD can be found at the USAID website; http://www.usaid.gov/business/business_opportunities/cib/. The "USAID Consolidated List of Approved ARVs" can be found at http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html,

Advance approval is hereby given under the [AIDAR provision 752.225-70, "Source, Origin and Nationality Requirements"] [Mandatory Standard Provisions for U.S., Nongovernmental Recipients "USAID Eligibility Rules for Goods and Services"] [*other similar assistance agreement provision*] in your [contract] [grant] [cooperative agreement]". Office of Acquisition and Assistance "restricted commodity" approval of pharmaceuticals under ADS 312.5.3c or source, origin, and nationality waivers are not required for Approved ARVs. Such procurements must be made in accordance with terms of this AAPD.

[*This paragraph for contracts only:*] Advance consent [is hereby given] [is still required] for subcontracts solely for Approved ARVs in amounts in excess of the simplified acquisition threshold, under FAR clause 52.244-2, Subcontracts.

The above approval[s] [is] [are] given with the understanding that: (1) sufficient funding exists in the [contract] [agreement] to cover the expenditures; (2) the approval does not increase the total estimated amount of the [contract] [agreement]; and (3) additional funding will not be required. All other conditions of the [contract] [agreement] remain unchanged.

Please contact your CTO for technical questions on ARVs, e.g., in-country registration or if a particular ARV is an Approved ARV.