USAID
FROM THE AMERICAN PEOPLE

December 20, 2007

ACTION MEMO FOR THE ADMINISTRATOR

FROM: AA/GH, Kent D. Hill /s/

SUBJECT: Expedited Acquisition and Assistance Procedures for USAID's Activities and Programs Related to the Prevention, Care, and Treatment of HIV/AIDS

Recommendations

That you approve the following authorities to be included in Expedited Acquisition and Assistance Procedures for USAID's Activities and Programs Related to the Prevention, Care, and Treatment of HIV/AIDS ("HIV/AIDS Expedited Procedures") effective immediately through December 31, 2013:

1. Other than fully competitive procedures for the award or modification of assistance agreements.

Approve: ✓ 2-14-08 Disapprove: _____

2. Other than full and open competition for the award or modification of contracts.

Approve: ✓ 2-14-08 Disapprove: _____

3. A general source, origin, and nationality waiver, including motor vehicles and certain pharmaceuticals.

Approve: ✓ 2-14-08 Disapprove: _____

4. If you approve of recommendations 1 through 3, that you also approve the Determination and Findings for the Authorization of Less than Full and Open Competitive Procedures in the Modification or Award of Contracts, by indicating your approval at Tab 1.

Background

On December 19, 2000, three years before PEPFAR was announced and the Leadership Act was enacted, the Administrator approved Expedited Acquisition and Assistance Procedures for HIV/AIDS and Infectious Diseases (the "Original HIV/AIDS Expedited Procedures") to facilitate expedited acquisition and assistance processes for USAID's HIV/AIDS and Infectious Disease Initiatives on the basis of the urgent need to meet the ambitious targets set forth in that strategy. Today, PEPFAR and Leadership Act activities and programs continue to use the authorities granted in the Original HIV/AIDS Expedited Procedures. The Original HIV/AIDS Expedited Procedures expired on December 31, 2007.

In May 2007, President Bush announced his desire to double the United States' commitment to fighting HIV/AIDS and asked Congress to approve another five-year, $30 billion expansion of HIV/AIDS prevention, care, and treatment under PEPFAR through 2013. New HIV/AIDS Expedited Procedures are essential to USAID's ability to continue to respond quickly and effectively in meeting the critical needs of HIV/AIDS activities and programs, including PEPFAR activities and programs, through December 31, 2013. The decisions and authorities that you approve in this action memo will be the basis for the new expedited procedures.

Attachments:

Tab 1 – Determination and Findings for the Authorization of Less than Full and Open Competitive Procedures in the Modification or Award of Contracts
Tab 2 – General Background and Discussion
Tab 3 – Background on Recommendations
Tab 4 – Justification for Pharmaceuticals other than ARVs

CLEARANCE PAGE FOR ACTION MEMORANDUM on Expedited Acquisition and Assistance Procedures for Activities and Programs Related to the Prevention, Care, and Treatment of HIV/AIDS

Clearances:

Competition Advocate/LKopala /s/	Date 12/20/2007
GC/GH: SPascocello /s/	Date 12/20/2007
GH/DAA: GSteele /s/	Date 12/20/2007
GC/A&A: WBuckhold /s/	Date 12/20/2007
M/OAA/T: RHanna /s/	Date 12/20/2007
M/OAA/OD: MShauket /s/	Date 12/20/2007
A-GC: AHaiman /s/	Date 12/20/2007
LPA/CL: SSienkiewicz in draft /s/	Date 12/07
ES:	Date

GC/A&A: DPerone: dp: db: 2-0529:12/10/07: P: Expedited Acquisition and Assistance Procedures for Activities and Programs Related to the Prevention, Care, and Treatment of HIV/AIDS (12 07 07).doc

Determination and Findings for the Authorization of Less than Full and Open Competitive Procedures in the Modification or Award of Contracts

Determination

Pursuant to the authority set forth in AIDAR §706.302-70(b)(3)(ii), I have determined that it is necessary to use other than full and open competition in the modification and award of contracts related to USAID's HIV/AIDS activities and programs in order to avoid the impairment of U.S. foreign assistance and foreign policy objectives. This determination is made in consideration of the supporting findings set forth below, and will remain in force and effect from this date until December 31, 2013.

Supporting Findings

It is imperative that USAID have the ability to respond rapidly to the HIV/AIDS pandemic and to save lives. In certain instances, U.S. foreign policy interests require that the flow of assistance take place immediately, without following the standard, full, and open competitive procedures. The timeframe required by fully competitive contracting procedures, if followed, will not enable USAID to act in a manner consonant with U.S. foreign policy. The magnitude of the humanitarian crisis and the need for urgent assistance, coupled with the anticipated doubling of authorized PEPFAR funds and the continued need to reach annual Congressional milestones, necessitate the availability and use of expedited procedures.

In order to be able to quickly respond to changing assistance priorities, USAID must retain the flexibility in procurement and related activities that expedited procedures provide. For example, as missions design and develop programs under the second phase of PEPFAR, there may be a need to extend existing programs and their implementing instruments beyond their present scopes to bridge gaps between existing programs and activities and the establishment of new programs and activities. The provision of commodities and services must not be interrupted during programmatic switches. Continuation of treatment regimes such as ARVs is of utmost importance during program changeovers. Expedited procedures authorizing the extension of programs beyond their present scopes will enable USAID to maintain treatment regimes and patient relations, while moving the goals of the HIV/AIDS program forward.

Moreover, significant increases in funding, ambitious targets, and expanded programs have caused USAID to direct its contractors to scale-up their programs to meet demand. The net result is that contractors are reaching the total estimated cost ceilings of their contracts more quickly than anticipated, often years before the original completion date set forth in the contract. It is not necessarily in the best interest of USAID, PEPFAR, or U.S. foreign policy to stop programs prematurely and recompete contract awards for goods or services when a well-performing contractor that has accommodated USAID and PEPFAR's increased programmatic needs, approaches the total estimated cost ceiling of its contract significantly ahead of schedule. Accordingly, USAID needs the tools to conduct expedited procurements when the situation warrants.

USAID, by seeking offers from as many sources as is practicable under the circumstances, should be able to achieve robust competition, while ensuring that assistance is delivered timely and without a break in the supply of needed goods and services. Prior to using informal or expedited procedures for a particular procurement, as authorized by this determination, implementing officers will consider the feasibility of using full and open competitive procedures as described in the Federal Acquisition Regulation, as well as using small business Section 8(a) procurement authorities and minority serving institutions.

All uses of this authority will be documented by the pertinent contracting activity and the cognizant Contracting Officer (CO). In addition to this determination and findings, the CO will also need to include in the award file a written, albeit streamlined, justification for other than full and open competition (JOFOC), which includes a brief discussion of the supplies or services required to meet USAID's needs, a description of the efforts made to ensure solicitation from as many sources as possible under the circumstances (if under limited competition versus sole sourcing), a determination that the anticipated cost to the government is fair and reasonable, a description of any market research conducted (if applicable), and a statement of the actions taken to overcome barriers to competition in subsequent procurements. Contracting officer certification in accordance with FAR §6.303-2(a) (12) and approvals in accordance with FAR §6.304 are not required.

A copy of each JOFOC for an action of $100,000 or more shall be sent to the Agency Competition Advocate. M/OAA and GC/A&A will provide additional

written guidance on the use of these Expedited Procedures when awards or modifications are based on other than full and open competition. The continuing necessity for the Expedited Procedures set forth and approved herein shall be reviewed by the Assistant Administrator for Global Health on an annual basis.

Approve: ✓ /14 Disapprove:_____ Date:_____

2-14-08

General Background and Discussion

In January 2003, President George W. Bush announced PEPFAR, a five-year, $15 billion plan to address the global HIV/AIDS pandemic. On May 27, 2003, the Leadership Act became law, establishing the ambitious targets of treating 2 million infected people with anti-retroviral therapy, preventing 7 million new HIV infections, and caring for 10 million people infected or affected by HIV/AIDS. In May 2007, President Bush announced his desire to double the United States' commitment to fighting HIV/AIDS and asked Congress to approve another $30 billion over a five year period to further expand HIV/AIDS prevention, care, and treatment under PEPFAR. This action memorandum seeks the Administrator's approval of new HIV/AIDS Expedited Procedures from January 1, 2008 through December 31, 2013, commensurate with the end of the second phase of the PEPFAR initiative.

The Administrator's approval of the Original HIV/AIDS Expedited Procedures on December 19, 2000, was based on USAID's mandate to respond quickly to the urgent and critical needs of the HIV/AIDS, tuberculosis, and malaria crises. The Original HIV/AIDS Expedited Procedures consisted of five components, each of which were designed to expedite the delivery of HIV/AIDS, tuberculosis, and malaria programs: (1) approval of obligations that are not covered by existing strategic objectives per ADS 201.3.3.5; (2) authorization of less than fully competitive procedures in the award of new grants and cooperative agreements and authorization of non-competitive modifications to existing grants and cooperative agreements pursuant to ADS 303.5.5(d)(5) (now ADS 303.3.6.5(i)); (3) authorization for other than full and open competition in the award of contracts for goods and services per AIDAR 706.302-70(b)(3)(ii); (4) a reminder to Agency personnel of the importance of including small businesses, small disadvantaged businesses, and minority serving institutions in the implementation of the HIV/AIDS and tuberculosis programs; and (5) establishment of Geographic Code 935 as the countries of approved source, origin, and nationality code for the supply of goods and services, including motor vehicles. The Original HIV/AIDS Expedited Procedures expired on December 31, 2007.

The great need for HIV/AIDS Expedited Procedures continues and is critical to USAID's ability to expedite and implement activities undertaken in response to the HIV/AIDS pandemic, particularly during the second phase of PEPFAR. The new HIV/AIDS Expedited Procedures, however, will be available only for

USAID's HIV/AIDS activities and will not apply to tuberculosis or malaria activities. A separate action memorandum for tuberculosis and malaria activities will be submitted to you for your approval at a later time if expedited procedures are deemed necessary for either or both activities.

USAID has invoked the components of the Original HIV/AIDS Expedited Procedures in order to achieve the ambitious targets set forth by the USG in the HIV/AIDS and Infectious Disease Strategy. The Administrator's action memo approving the Original HIV/AIDS Expedited Procedures recognized that the meeting of the ambitious targets "will require procurement and assistance instruments to be in place in the shortest possible time." Furthermore, the approval established that "though full and open competition works well to maximize participation by the private sector community, we will need expedited action to meet the targets." This concept was echoed in the Conference Report accompanying the FY 2001 Appropriations Act that stated:

> The managers are aware that the HIV/AIDS and tuberculosis crises require extraordinary efforts on the part of the USG. USAID is encouraged to use, as appropriate, its existing waiver authorities regarding financing and procurement of goods and services, and grant making, in order to expedite the provision of HIV/AIDS and tuberculosis assistance and enhance the efficiency of that assistance.

With the President's creation of PEPFAR and Congress' authorization of the U.S. Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, the United States recognized that the "magnitude and scope of the HIV/AIDS crisis demands a comprehensive, long-term international response focused upon addressing the causes, reducing the spread, and ameliorating the consequences of the HIV/AIDS pandemic" and its "capacity to lead and enhance the effectiveness of the international community's response." Today, more than four years later, PEPFAR is on track to meet its ambitious five-year goals of supporting treatment for two million people, preventing seven million new infections, and caring for ten million people, including orphans and vulnerable children (the "2-7-10 Goals"). While significant accomplishments have been achieved, the USG continues to make the fight against the HIV/AIDS pandemic a top priority, not only for humanitarian reasons, but because the HIV/AIDS crisis threatens the prosperity, stability, and development of nations around the world.

In May 2007, President Bush announced his desire to double the United States' commitment to fighting HIV/AIDS for the second five-year phase of PEPFAR and asked Congress to approve another $30 billion to further expand life-saving efforts supporting the treatment for 2.5 million people, preventing more than 12 million new infections, and caring for more than 12 million people, including five million orphans and vulnerable children.

Time remains of the essence in the award and implementation of USAID's HIV/AIDS activities and programs. USAID still requires HIV/AIDS Expedited Procedures to respond quickly and appropriately to urgent and critical demands arising in its program of support to fight the HIV/AIDS pandemic and to avoid any unacceptable delays in program implementation. Such demands may include the rapid provision of assistance under critical HIV/AIDS initiatives, such as ensuring the supply and provision of life-saving antiretrovirals (ARVs) to AIDS patients, and in meeting other crucial USG priorities. In order to be able to quickly respond to changing assistance priorities, USAID must retain the flexibility in procurement and related procedures that expedited procedures provide. Additionally, as missions design and develop programs under the second phase of PEPFAR, there may be a need to extend existing programs and their implementing instruments beyond their present scopes to bridge gaps between existing programs and activities and the establishment of new programs and activities. The provision of commodities and services must not be interrupted during programmatic switches. Continuation of treatment regimes, such as ARVs, is of utmost importance during program changeovers, and authorities permitting the extension of programs beyond their present scopes will enable USAID to maintain treatment regimes and patient relations, while moving the goals of the HIV/AIDS program forward.

The HIV/AIDS Expedited Procedures recommended and authorized by this action memo will continue to assist USAID, particularly USAID missions, in streamlining and ensuring the efficiency of its HIV/AIDS efforts. USAID, however, will rely upon such authorities only in appropriate situations, based on the circumstances presented. USAID has utilized the Original HIV/AIDS Expedited Procedures in appropriate instances to facilitate the quick and/or continued implementation of critical HIV/AIDS prevention, care, and treatment activities. For example, missions have utilized the Original HIV/AIDS Expedited Procedures to increase the total estimated amount ("ceiling") on acquisition and assistance awards when USAID directed the contractor or grantee to scale-up

activities under the agreement in order to reach annual, congressionally-mandated PEPFAR targets. As a result of the scale-up of activities, the contractor or grantee may reach the existing ceiling years in advance of the agreement's completion date. USAID has utilized the Original HIV/AIDS Expedited Procedures to raise the ceiling on these instruments, allow the activities to continue and targets to be met, and ensure that there is sufficient time for a competitive process to take place for the follow-on award.

USAID has and will continue to utilize full and open competition in HIV/AIDS programs, and it is expected that full and open competition will continue to be the primary method used to award contracts, grants, and cooperative agreements for HIV/AIDS programs, unless the expediency described above and the elements set forth in FAR §6.303-2(a)(1) – (11) and AIDAR §706.302-70(c)(2) justify the need to use less than fully competitive procedures.

The Original HIV/AIDS Expedited Procedures approved by the Administrator in 2000 included a source, origin, and nationality waiver that did not include pharmaceuticals. We conclude that for programmatic purposes, procurement of additional pharmaceuticals from non-U.S. sources is necessary for timely program implementation of HIV/AIDS activities and to develop local capacity. Therefore, we recommend that the new HIV/AIDS Expedited Procedures include source, origin, and nationality waivers for ARVs, other pharmaceuticals, and motor vehicles, in addition to a general waiver for commodities and services.

We recommend that you approve the HIV/AIDS Expedited Procedures through December 31, 2013, commensurate with the proposed end of the second phase of the PEPFAR initiative.

Background on Recommendations

1. Recommendation No. 1 -Grants and Cooperative Agreements: Authorization for Other than Fully Competitive Procedures. In keeping with the Federal Grant and Cooperative Agreement Act, USAID encourages competition in the award of grants and cooperative agreements in order to identify and fund the best partners to achieve program objectives. In 2000, the Administrator approved a recommendation to authorize the use of other than fully competitive procedures in making certain assistance awards. The approval authorized: (1) non-competitive modifications to existing assistance awards, and (2) the award of new assistance agreements using less than fully competitive procedures. The basis for both expedited procedures was the Administrator's determination that in certain appropriate instances, making such modifications or awards without the delay inherent in the standard competitive processes was critical to the objectives of the United States' foreign assistance program.

In the past seven years, USAID has utilized this authority judiciously; indeed, USAID usually awards assistance instruments using fully competitive procedures. During this period, however, there have also been urgent and vital USAID HIV/AIDS assistance activities that have relied on this expedited award authority. The continued need to expedite HIV/AIDS programming to meet critical U.S. foreign policy objectives still exists. Accordingly, we recommend that you again authorize the use of other than fully competitive procedures for assistance pursuant to ADS 303.3.6.5.i. The current limitation of two years for non-competitive extensions of existing awards would be maintained. This expedited procedure would also cover modifications and follow-on awards in excess of $20 million as discussed in ADS 303.3.6.6.c.

2. Recommendation No. 2. Procurement of Goods and Services through Contracts: Authorization for Other than Full and Open Competition.

On December 19, 2000, pursuant to the Agency for International Development Acquisition Regulation (AIDAR), the Administrator made a determination and finding that compliance with full and open competitive procedures would, in certain circumstances, impair foreign assistance objectives and be inconsistent with the fulfillment of the foreign assistance program. See AIDAR § 706.302-70(b) (3) (ii).

Accordingly, the Administrator approved the use of less than full and open competitive processes in the award or modification of contracts. USAID has utilized this authority judiciously in the past and has issued most contracts in support of HIV/AIDS programs and activities on a full and open competitive basis. As the continued need to expedite the Agency's HIV/AIDS program in support of critical U.S. foreign policy objectives still exists, we recommend that this authority be reauthorized to permit flexible and expedited procurement procedures for USAID direct contracting for the delivery of goods and services. We further recommend that on an as-needed basis, such procurements be undertaken through limited competitive procedures that are quicker and less labor-intensive than the full and open competitive procedures prescribed by the Federal Acquisition Regulation (FAR). As in Recommendation No. 1 above, this authority would apply to: (1) all follow-on extensions and modifications of existing contracts (again, with the two-year limit described above), and (2) new procurements.

Pursuant to AIDAR §706.302-70(b)(3)(ii), you may determine in writing, with supporting findings, that compliance with full and open competitive procedures would, in certain instances, impair foreign assistance objectives and be inconsistent with the fulfillment of a foreign assistance program. You have the authority to make such a determination as to USAID's entire HIV/AIDS program, including the programs and activities which will be developed in coordination with the Office of the Global AIDS Coordinator and the other PEPFAR agencies, and implemented by USAID missions, the Global Health Bureau, and other Agency personnel. The authority to use less than full and open competition requirements would be utilized for activities where the impact of the Agency's HIV/AIDS activities and U.S. assistance will be needed on an expedited timeframe. Your determination and findings in support of this authority are attached to the action memo as Tab 1. The Agency Competition Advocate has reviewed and concurred with your determination and findings.

Your approval of this recommendation authorizes USAID Contracting Officers to use other than full and open competitive processes to expedite the acquisition process. While the publicizing of proposed contract actions would not be necessary, solicitation would be made from as many sources as practicable, given the totality of the circumstances presented by the particular procurement

under consideration. While USAID's preference is to solicit from a number of sources, there may be circumstances in which sole source awards will be necessary.

Your approval of other than full and open competition, including the supporting determination and findings and the required Contracting Officer documentation as detailed in Tab 3, will constitute the written justification as required by FAR§ 6.303, AIDAR § 706.302-70(c) (2), and ADS 302.5.8, except that contracting officer certification prescribed by FAR §6.303-2(a) (12) and the approvals and prescribed by FAR §6.304 are not required.

3. Recommendation No. 3. Source, Origin, and Nationality Waiver.

a. General Waiver to Code 935. In 2000, pursuant to the general authority to use foreign assistance funds for procurement, the Foreign Assistance Act of 1961, as amended, Section 604(a), and the specific authority at 22 CFR § 228.50, the Administrator approved the establishment of Geographic Code 935 (which includes all countries, including Iraq, and excludes only certain foreign policy restricted countries) as the applicable authorized source, origin, and nationality code for any goods and services procured in support of USAID's HIV/AIDS activities and programs.

Ready availability of services and commodities has proven essential to the quick start and smooth implementation of many of our HIV/AIDS activities and programs, including PEPFAR. For this reason, we recommend that Code 935 be maintained as the applicable source, origin, and nationality code for USAID's HIV/AIDS activities and programs. Code 935 would be fully applicable for procurements at both the prime contract and subcontract level (including procurements under grants and cooperative agreements).

Condoms and rapid test kits are not included in this general source, origin, and nationality waiver. Motor vehicles and pharmaceuticals are included in this source, origin, and nationality waiver. See sections b, c, and d which follow for special conditions pertaining to source, origin, and nationality waivers for motor vehicles and pharmaceuticals.

b. Motor Vehicle Source, Origin, and Nationality Waiver. Motor vehicles not manufactured in the U.S. were included in the Original HIV/AIDS Expedited Procedures, and we recommend that motor vehicles be included in these HIV/AIDS Expedited Procedures. The emergency nature of the HIV/AIDS epidemic continues to meet the "special circumstances" standard of section 636(i). Even more so than with other commodities, the approval process for the purchase of non-U.S. produced motor vehicles adds additional time and costs, diverting staff resources of USAID and implementers from direct prevention, treatment, and care activities. In most of the areas where USAID is conducting HIV/AIDS activities, no maintenance facilities exist for U.S.-produced vehicles, spare parts are not readily available for such vehicles, and/or the right-handed steering columns are necessary. In addition, U.S.-produced vehicles invariably have to be shipped from the United States, adding further delay in implementation of HIV/AIDS activities.

Procurement of non-U.S. produced motor vehicles will be held to a minimum and carried out only when vehicles of the type needed are not produced in the U.S., not available from a U.S. producer for shipment to the recipient country, or when service or availability of spare parts for U.S.-produced vehicles is inadequate in the recipient country. As required in the Original HIV/AIDS Expedited Procedures, a preference will continue for motor vehicles available in the cooperating country or produced in Code 941 countries, and all purchases of non-U.S. produced vehicles will be required to be documented.

Your approval above constitutes the required "special circumstance" finding required for non-U.S. manufactured motor vehicles under section 636(i) of the Foreign Assistance Act of 1961, as amended (FAA).

c. Antiretrovirals (ARVs) Source, Origin, and Nationality Waiver. On April 29, 2005, the Administrator approved a source, origin, and nationality waiver and restricted commodity approval for the procurement of the ARVs produced by innovator companies, but manufactured in specific non-U.S. sites. (An innovator company is a brand-name company that has U.S. patent protection for an ARV, giving that company the sole right to sell that drug for a certain period of time in the U.S.). There are established procedures for the approval of such ARVs in AAPD 07-01. The ARV source, origin, and nationality waiver for these drugs expires on September 30, 2008. We recommend that USAID continue to facilitate the purchase of such non-U.S. innovator ARVs by extending this source, origin,

and nationality waiver to December 31, 2013, so that the expiration date is commensurate with the rest of this Expedited Procedures package. Your approval constitutes a waiver for the ARVs described above.

d. Other Pharmaceuticals Source, Origin, and Nationality Waiver. We are recommending that this source, origin, and nationality waiver include those "other pharmaceuticals" which are:

i) manufactured at a site approved by a Stringent Regulatory Authority (SRA); or
ii) offered for distribution by the International Dispensary Association Foundation (IDA), Mission Pharma, or UNICEF; or

iii) otherwise specifically technically approved by GH/OHA/SCMS, as confirmed by GH/OHA/SCMS prior to purchase.

The justification for these pharmaceuticals is at Tab 4. Your approval constitutes a waiver for the above-described pharmaceuticals.

Justification for Pharmaceuticals Other than ARVs

ADS Chapter 312 - Eligibility of Commodities, sections 312.5.3c and E312.5.3c, require approval prior to purchase of certain offshore "restricted commodities," including pharmaceuticals. Determinations to approve purchases of offshore pharmaceuticals require that the issues in the discussion below be considered. The discussion of these issues in this HIV/AIDS Expedited Procedures document satisfies the requirement of ADS 312.5.3c.

1. Source/Origin Considerations. 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 pharmaceuticals that are critical to the PEPFAR program. It is the stated policy of the PEPFAR program that the Emergency Plan will purchase the lowest-cost drugs, regardless of origin, when they have been demonstrated to be safe, effective, and of high quality and will provide such drugs in a timely and efficient manner, including the purchase and/or provision of such drugs in instances of stock-outs where time is of the essence. This waiver will permit OHA/SCMS to create and maintain a list of safe and effective multi-source generic pharmaceuticals for expedited purchase and/or provision.

A critical objective of the PEPFAR program is the sustainability of HIV/AIDS host-country programs. This requires USAID to use existing sources of pharmaceuticals (with due regard for safety, efficacy, and quality) to provide the readily available, adequate stocks of drugs. Frequently, pharmaceuticals being prescribed in in-country programs do not originate from the U.S., and, in many cases, equivalent U.S.-manufactured pharmaceuticals are not registered by host government drug regulatory authorities. In part, this is due to international price competition and local registration requirements. Moreover, meeting the sustainability objective also requires building the supply capacities of those in-country programs which USAID supports. In order to achieve this, USAID must focus on using sources and manufacturers that the host government has approved or will be using.

Without access to high quality, low-cost, primarily generic pharmaceuticals that are approved for use, PEPFAR country programs are unable to distribute pharmaceuticals to those who need them and are unable to reach prevention and treatment program targets.

Due to international price competition and local registration requirements, there are virtually no U.S.-origin generic drugs available in the developing countries in which USAID is implementing health programs. In addition, in order to build up the supply capacity of the in-country programs USAID is supporting, USAID must focus on using sources and manufacturers that the host government has approved or will be using.

2. Cost. With regard to the cost differential consideration, i.e., that the U.S. cost be at least 50% more than the non-U.S. cost, experience has shown that non-U.S.-origin generic drugs nearly always meet the requirement. In fact, these drugs are often an order of magnitude less expensive. An analysis of over 200 commonly used multi-source generics showed a median price ratio between international prices and those available from the Federal Supply Schedule of 1:3.8. In other words, on the FSS the same product was nearly four times more expensive than the non-US generic price.

3. Safety, Efficacy, and Quality. ADS Chapter 312 further requires that information is available to attest to the safety, efficacy, and quality of pharmaceuticals that are not Food and Drug Administration (FDA)-approved. We recommend that this source, origin and nationality waiver include those other pharmaceuticals which are:

a. manufactured at a site approved by a Stringent Regulatory Authority (SRA);
b. sold by the International Dispensary Association Foundation (IDA), Mission Pharma, or UNICEF; or
c. otherwise approved by GH/OHA/SCMS.

a. Stringent Regulatory Authorities (SRAs). Because the SRAs designated as such by USAID have standards similar to the FDA, SRA approval meets the safety, efficacy, and quality requirements of ADS Chapter 312. SRA approval was considered adequate for ARVs under the Administrator's 2005 waiver for the purchase of pharmaceuticals and medical equipment and supplies.

USAID practice is that an SRA is a national drug regulatory authority (NDRA) that closely resembles FDA in its operations. Currently, USAID has designated as SRAs the following NDRAs that participate as members or observers in the International Conference on Harmonization:

- Japanese Ministry of Health, Labor, and Welfare;
- European Agency for the Evaluation of Medicinal Products (EMEA);
- European Free Trade Area (represented by the Swiss Medic); and
- Therapeutic Products Directorate, Health Canada (observer)

b. IDA, Mission Pharma, and UNICEF. Based on USAID's long experience and an inspection visit by a USAID team, USAID has determined that these three pharmaceutical wholesalers have systems in place that adequately address safety, efficacy, and quality of the products they sell.

IDA, UNICEF, and Mission Pharma are organizations that have well-established reputations for providing high quality generic pharmaceuticals, medical equipment, and supplies to governments, United Nations agencies, and NGOs in developing countries. Another value-added component of IDA, UNICEF, and Mission Pharma is that these wholesalers actively strive to register appropriate drug products in the least-developed countries in which they work. Active efforts to achieve drug registration greatly enhance USAID's ability to provide needed drug products in a timely manner. A waiver for the contract with the Partnership for the Supply Chain Management (PFSCM) approved in 2006 included IDA, Mission Pharma, and UNICEF as sources of safe, effective, quality pharmaceuticals, and medical equipment and supplies. Our experience with them continues to be positive

IDA is the world's largest not-for-profit provider of pharmaceuticals and medical supplies, offering a wide range of quality-assured products from stock. IDA has been USAID's principal wholesaler for non-U.S. pharmaceuticals and has been used by USAID on a case-by-case waiver basis for both large and small procurements of non-U.S. pharmaceuticals. IDA is a preferred supplier to the World Health Organization (WHO), the International Committee of the Red Cross, Doctors Without Borders, the U.N. High Commissioner for Refugees, and, as mentioned above, has previously supplied pharmaceuticals to USAID-funded projects.

UNICEF, established in 1946, has a mandate to provide supplies to both private and public sector health and population program recipients throughout the developing world. A central warehouse is located in Copenhagen, Denmark and HIV/AIDS drugs and supplies are warehoused and distributed from this site.

UNICEF requires all manufacturers responding to its solicitations to be pre-approved by WHO and to demonstrate annually that they comply with applicable

WHO standards. WHO's Geneva headquarters acts as an adviser to UNICEF on matters related to the quality of pharmaceutical and biological products and has formulated criteria for evaluating the acceptability of vaccines for purchase by UN agencies. All quality assurance functions are provided to UNICEF by WHO. These include random lot testing, inspection of the suppliers' facilities and the National Control Authority Laboratory by qualified experts, periodic re-inspections, and follow-up investigations of reported adverse events. Procuring through UNICEF is one of the most effective means to ensure that medications of known quality are procured.

Founded in 1975, **Mission Pharma** is a for-profit organization with an original objective of supplying low-cost generic pharmaceuticals to missionary clinics associated with Scandinavian churches. It has since expanded and is now one of the world's leading suppliers of generic pharmaceuticals and medical devices to governments, UN agencies, and NGOs in developing countries. In addition to supplying products from WHO pre-qualified manufacturers, Mission Pharma runs its own comprehensive prequalification system, based on the following criteria:

- Valid manufacturer's license and Good Manufacturing Practice (GMP) certificate according to WHO guidelines.
- Assessment of Site Master File
- Evaluation of product dossiers including conducted bioequivalence studies.
- Performing a formalized GMP audit at the manufacturing site.
- Verification of quality control procedures and source of Active Pharmaceutical Ingredient (API).

In addition, Mission Pharma has a quality control system for verifying product quality that includes inspections of the actual product and a comparison of Certificates of Analysis against finished product and API specifications. It uses a network of qualified independent laboratories undertaking further analysis of the product quality when required. In case of product complaint or recall, there are Standard Operating Procedures to ensure that appropriate corrective and preventive actions are taken.

The Trip Report concluded that IDA, UNICEF, and Mission Pharma all have extensive experience in procuring, distributing, and monitoring the quality of pharmaceuticals, medical equipment, and supplies in least-developed countries throughout the world. The general findings of the Trip Report were:

(1) Prequalification. In reviewing the quality testing and monitoring systems, it is our opinion that these three organizations make significant efforts to assure drug quality. Each of the three organizations requires that suppliers undergo a rigorous prequalification process. These processes include initial applications by the supplier to document business solvency and capacity, ability to supply needed products, and quality of products provided. If a preliminary application is approved, a manufacturing site inspection is scheduled to assess compliance with GMP. Criteria used by inspectors are GMP criteria recommended by the World Health Organization. After a supplier has successfully completed the prequalification process, routine follow-up GMP inspections are conducted at three-year intervals to assure continuing compliance.

(2) Testing. In addition to the prequalification process, samples from the new supplier's drug products are routinely subject to visual inspection and selected testing in reference laboratories to confirm the content and quality of the drugs provided at each organization's facilities.

(3) Warehousing. The team also reviewed warehousing practices at each of the three companies. It is apparent that state-of-the-art warehouse equipment and facilities are fully available at these three organizations. Standard Operating Procedures are in place to maintain proper control of inventory and related documents and records.

This waiver is based primarily on Agency experience with the above-named organizations. We are working with GH/HIDN, OAA/T, and OFDA on objective standards under which other organizations may "pre-qualify" as pharmaceutical wholesalers.

c. Approval by GH/OHA/SCMS. These HIV/AIDS Program Procedures contain the Other Pharmaceuticals Source, Origin and Nationality Waiver in Part F and there will not be a need for individual source, origin and nationality waivers for non-ARV HIV/AIDS pharmaceuticals.

However, GH/OHA/SCMS must confirm prior to purchase that the specific non-ARV pharmaceuticals have been (a) manufactured at a site approved by a Stringent Regulatory Authority (SRA); or (b) offered for distribution by the IDA, Missionpharma or UNICEF; or (c) been technically approved previously by GH/OHA/SCMS. If GH/OHA/SCMS has provided this confirmation, approval from M/OAA/T/COM is not required. A list of non-ARV pharmaceuticals approved by GH/OHA/SCMS will be included on the Global

Health external internet site at:
http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html

5. Additional Quality Assurance (QA) Testing. As a part of its efforts to ensure ongoing quality of supplies and gather independent data on the QA procedures of its suppliers, OHA/SCMS, under its contract with the Partnership for Supply Chain Management, has procedures for QA testing of pharmaceuticals. These procedures will be exercised to conduct testing on a case-by-case basis in those situations where GH/OHA/SCMS determines that the specific pharmaceuticals proposed for purchase have not been manufactured at a site approved by a Stringent Regulatory Authority (SRA); are not being purchased from IDA, Missionharma, or UNICEF directly; or, for which GH/OHA/SCMS has not provided previous technical approval.

6. US Patent Laws and Express Authorization. Multi-source generics are off-patent and therefore do not infringe U.S. patents or require express authorization by the U.S. patent holder. For non-generics, the supplier will be required to certify on their invoices that items supplied will not infringe upon any U.S. patents.

Approve: ___/s/_____
M/OAA/T/COM

Disapprove: _____
M/OAA/T/COM

Date: __12/19/2007_____