Questions and Answers for the Public
Donating Drugs to International Humanitarian Relief Efforts

The following set of Questions and Answers is intended to provide information to non-profit organizations (e.g., charities, state-operated medical response groups, non-governmental organizations) interested in donating drugs or sending medical groups with pre-arranged medical supplies for international humanitarian efforts. These Q&As also include information on the regulatory requirements for sending (exporting) drugs as part of international humanitarian relief efforts.

FDA discourages individual consumers and small groups from donating drugs to relief efforts because these donations may not meet the legal requirements for sending drugs to other countries. Generally, drug donations from individual consumers will be destroyed.

Drug manufacturers and distributors interested in donating drugs to an international relief effort should read the following information but are also advised to refer to the FDA's *Guidance for Industry Exports Under the FDA Export Reform and Enhancement Act of 1996*.

Questions and Answers for the Public
Donating Drugs to International Humanitarian Relief Efforts

Q1. Should individuals or small groups donate drugs for humanitarian relief efforts?

A. No. Drugs donated by individuals, families, or small groups, whether already in the home or purchased with the intention to donate, may not meet the requirements for use in a humanitarian effort. The donated drugs will likely be destroyed, resulting in the use of significant resources (time, effort, and money) for sorting, organizing, and destroying the drugs.

Q2. Why should drug donations from individuals or small groups be avoided?

A. Drugs should be donated in large enough quantities (generally at least several cases of product) to make the efforts of receiving, sorting, and distributing cost-effective to the relief organization. Generally, drug donations from individuals and small groups will be destroyed. For drug donations to be eligible for international relief efforts, there should also be assurance of the drug's safety, effectiveness, and product quality. See also Q5 for more information.

Q3. How can individuals or small groups help with humanitarian relief efforts?

A. Individuals, families, or small groups interested in contributing to international humanitarian relief efforts should contact one of the following organizations for more information:

- United States Agency for International Development [USAID] (http://www.usaid.gov)
- Center for International Disaster Information [CIDI] (http://www.cidi.org)
- American Red Cross (http://www.redcross.org)

All of these organizations agree that the most effective way to help international relief efforts is through the donation of money.

Q4. Why should drug donations be limited to large quantities?

A. A significant amount of time and effort on the part of the relief agency is required to sort and organize donations before sending them to the country in need. Sorting and organizing many small donations requires significantly more time than what is needed for a few large donations. This means the time and money of the relief agency are not spent effectively.

Q5. What is meant by "assurance of the drug's safety, effectiveness, and product quality?"

A. As part of the FDA approval process, drug products must meet specific standards for safety, effectiveness, and labeling in order to ensure that health care providers and patients have information necessary to understand a drug product's risk as well as its safe and effective uses. Additionally, firms are required to demonstrate that their manufacturing processes reliably produce drug products of expected identity, strength, quality and purity, as well as demonstrate that these products are properly transported and stored.

Drugs are given an expiration date based on testing to assure strength, quality, and purity, and are to be stored and handled according to the labeled storage conditions.

Q6. Can an organization donate drugs that have expired or are near expiration?

A. FDA and the World Health Organization (WHO) strongly discourage donation of expired drugs, even to affected nations during an emergency or crisis. Additionally, nations may consider the dispensing of expired drugs to be illegal, including during a crisis. Guidelines from the WHO state that drugs with less than one year before their expiration date will automatically be destroyed.[1] Depending on the nature of the emergency, and on a case-by-case basis, FDA is prepared to exercise enforcement discretion on the exportation of a designated product as long as it is to fulfill a request from the importing country and found acceptable by that country; and the expiration issues have been evaluated by an appropriate component of FDA, or when reasonable assurance is provided to the receiving country and FDA that the product meets quality specifications. The FDA would not object to the donation of drugs that are past or within one year of the expiration date shown on the label when provided with sufficient information to show the expired lot(s) are safe and effective. Furthermore, the FDA expects that no U.S. marketplace shortage would occur due to the exportation of the donated drugs, and that within expiry supplies would be preferentially used before the expired or near expiration supply, if practical. FDA has and will allow the use of a drug under similar circumstances when needed to alleviate a U.S. shortage.

Q7. Can an organization donate drug samples intended for a physician's office?

A. The World Health Organization discourages the donation of drug samples from any organization other than a manufacturer, as these drug samples will likely be refused and/or destroyed. CDER also strongly discourages donation of drug samples by any organization other than the manufacturer. If, however, a manufacturer is interested in

[1] World Health Organization "Guidelines for Drug Donations" Revised 1999. WHO/EDM/PAR/99.4. http://whqlibdoc.who.int/hq/1999/who_edm_par_99.4.pdf

donating drug samples to a relief effort, the donation must comply with 21 C.F.R. § 203.39.

Q8. What drugs should be donated to international humanitarian relief efforts?

A. In addition to meeting the requirements outlined above, donations should be limited to drugs that are specifically requested by either the government of the affected nation or a relief organization involved directly in relief efforts. Requests for specific drugs may be found through resources such as the USAID or CIDI websites. See response to Q3 for websites.

WHO has developed and periodically updates a list of drugs likely to be needed during emergency humanitarian relief efforts. This list is a general guideline, and should not be viewed as a specific request for drugs. Organizations should still ensure that products have been requested by the affected country or relief organization before attempting to donate any drug product. The WHO Model Lists of Essential Medicines can be found at http://www.who.int/medicines/publications/essentialmedicines/en/.

Q9. What about organizations transporting pre-constructed medical supply caches as part of a mobile medical unit responding to an international humanitarian relief effort?

A. Organizations sending a mobile medical unit/team with its own medical supplies should review the inventory to ensure all products contained in the cache are in compliance with the Federal Food, Drug, and Cosmetic Act (FFDCA) and/or Public Health Service Act (PHSA) as appropriate (i.e., "FDA approved"). Products that are not approved for commercial use in the U.S. will need to meet additional regulatory requirements before being exported outside the U.S.[2]

Q10. Are there particular drugs used in relief efforts that are not FDA approved?

A. Yes. The FDA is aware of medically necessary drugs that are currently sold in the U.S. without FDA approval, including some drugs used in emergency room and disaster relief settings. In order to assist organizations, presented below is a partial list of drugs

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[2] FDA's current position on exportation of drugs is explained in the "Guidance for Industry Exports Under the FDA Export Reform and Enhancement Act of 1996," which can be found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125799.htm.
FDA's current position on marketed unapproved drugs is explained in the "Guidance for FDA Staff and Industry Marketed Unapproved Drugs - Compliance Policy Guide," which can be found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070290.pdf.

that may be present in a disaster relief cache despite the lack of FDA approval. This list is not inclusive of all possible unapproved products.

Atropine sulfate injection (Note: the Ansyr® syringe is an approved product)
Calcium gluconate injection
Ephedrine injection
Epinephrine injection
Methylene blue injection
Neostigmine injection
Phenobarbital tablets, injection & syrup
Amyl nitrite inhalants
Sodium thiosulfate injection and sodium nitrite injection (Note: Nithiodote™ is an approved co-packaged product.)
Thiopental injection
Atropine ophthalmic solution
Fluorescein ophthalmic drops and/or strips
Tetracaine ophthalmic solution
Sodium fluoride oral products
Barium sulfate
Prenatal vitamins

Q11. How can an organization determine if a drug is FDA approved?

A. There are two online resources that can be used to determine if a particular drug is FDA approved.
The Orange Book - http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm
Drugs@FDA - http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm

Information necessary to confirm the approval status of a drug includes:

- Product Name (brand or generic name)
- Presentation
    - Dosage form (auto-injector, IV, tablet, capsule…)
    - Strength
- Manufacturer

The above resources can be used to search by generic drug name or brand name (also called the proprietary name). Results will indicate the manufacturers/applicant holders and presentations that are currently approved by the FDA. Organizations should check both of these resources in order to develop as complete a picture as possible regarding FDA approval.

Q12. What if an organization has one or more drugs that have been specifically requested and would like to send them to the affected country?

A. Drugs intended to be shipped to a foreign country as part of a humanitarian relief effort are considered exports, and therefore, need to meet certain legal requirements under the FFDCA and the PHSA. Drugs that have FDA approval (e.g., are in full compliance with the FFDCA or the PHSA) may be exported without meeting any additional regulatory requirements. If a drug does not have FDA approval or does not conform with an FDA approval, then additional regulatory requirements must be met before the drug can be exported.[2]

It is important to note that even though a drug may be legally exported from the U.S., it may not be allowed into the affected country unless the drug is specifically requested for the relief efforts. Drugs that are not allowed entry to a foreign country and are returned to the United States will be subject to the Imports requirements of the FFDCA. It is recommended that rejected drugs be destroyed.

Q13. What does an organization need to do if the drug product has been requested for an international humanitarian relief effort, or is part of a pre-constructed medical cache, but is not FDA approved?

A. In order to export a drug that does not have FDA approval, the donating organization must meet certain requirements[2] as listed in the FFDCA.

Q14. If there are additional questions, who can be contacted at FDA?

If an organization can document the need their donation will meet and has specific questions or concerns about a particular drug that does not have FDA approval, based on a search of Drugs@FDA and the Orange Book, they may contact CDER's Division of Drug Information at 1-888-463-6332 for assistance in determining the requirements for exportation of the drug.