

**A Proposal for Collaboration Between
The FDA and the Human Milk Banking Association of North America
To Assure the Quality and Safety of Donor Human Milk**

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There appears to be an increasing need for federal oversight of donor human milk banking, as witnessed by current concern expressed at USDA over use of donor human milk for WIC recipients, and a few random attempts by breastfeeding mothers to give away or sell their milk locally or via the Internet. With this need in mind, and given the fact that the Human Milk Banking Association of North America (HMBANA) has developed guidelines under which member banks have been operating since 1991, a collaborative effort between FDA and HMBANA to set federal guidelines is an ideal leveraging opportunity.

FDA staff have regularly given input into the development and updating of the *Guidelines* since 1987. From 1987 until 1990 when the initial guidelines were finally completed, two FDA staff members, John Wallingford, PhD, of the Clinical Nutrition Branch, Center for Food Safety, and James Weixel of the Consumer Safety office reviewed each draft of the proposed guidelines. Dr. Wallingford even found funding for testing of the milk processing procedure to ascertain that it would destroy HIV while minimizing damage to the unique immunologic and nutritional properties of the milk. Both of men continued to advise HMBANA until they left the FDA. Dr. Edgar Marcuse also reviewed the initial guidelines as a representative of the American Academy of Pediatrics Committee on Infectious Disease.

Since 1990 the *Guidelines* have been updated annually, and you have before you the 1999 edition. The six US milk banks and one Canadian milk bank will be meeting the first week in May to again review the guidelines and the standard operating procedures for the individual milk banks. In 1991 HMBANA sent a representative to the Tissue and Organ Transplantation Regulation hearing, and she was one of the authors of the final document *USPHS Guidelines for Prevention of Transmission of HIV through Transplantation of Human Tissue and Organs*. These guidelines have been incorporated into HMBANA's guidelines were applicable.

HMBANA's guidelines include verbal and written questionnaires, which are closely patterned after blood banking screening forms, with a few additional questions. For example, potential milk bank donors are asked about both smoking and alcohol consumption. We do not accept smokers as donors, nor do we accept milk that has been pumped less than 12 hours after an occasional alcoholic drink. We also require a written statement from both the donor's physician and her baby's physician that this mother will be an appropriate donor.

A little background on donor milk banking in the US might give you some perspective on the issues involved. There are currently six milk banks operating in the country. Four of them are within tertiary medical centers and two are freestanding non-profits associated with tertiary medical centers. The oldest milk bank, located at Christiana Hospital in Delaware, has been in operation since 1943, and the newest opened last year in Austin, Texas as a collaborative effort among three level-3 hospitals.

All milk is donated. There is no payment to donors. Milk is only dispensed to a hospital, or on physician order to an individual recipient. Recipients are charged a processing fee of \$2.50 per ounce to help defray the costs of donor testing and the processing of the milk. As will other health care, no recipient is denied service based on lack of ability to pay.

Obviously, with so few facilities, the need for donor milk across the country is met through a collaborative effort. This alone has motivated member banks to agree on both donor screening procedures and milk processing procedures. An additional reason for FDA recognition of the guidelines is that of necessity milk is shipped all over the country from most of the milk banks. Both California and New York have licensing requirements by statute for milk banks, which are patterned after the HMBANA guidelines. However, New York's only milk bank at this time is an in-house research facility.

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With the increased recognition in the literature of the superiority of human milk for human infants, especially for preterm and sick infants, other tertiary level hospitals around the country are considering opening donor milk banks. Some are also negotiating to become satellite banks which to serve as collection depots for donors to drop off milk and dispensaries for processed milk.

In 1999 among the six banks we processed and distributed about 200,000 ounces. Our milk bank at WakeMed in Raleigh is the third largest bank, and we distributed almost 55,000 ounces. The majority of the recipients at our bank are preterm infants in our own and other neonatal intensive care units; however, since the premies are so small they usually take less volume than the older babies who are at home. Milk banks also supplied milk to several adult cancer patients and some transplant patients. Human milk is the ideal source of IgA and other immunologic factors that these patients need after chemotherapy.

Donor human milk has been safely used since the beginning of recorded history to provide appropriate nutrition to infants whose mothers could not breastfeed them. Until the early 20th century most of the milk was provided via wet nursing. There is even a report in the 1911 *Journal of the American Medical Association* describing a home in Boston for wet nurses who were medically supervised by a physician. Since that time hospitals have stored pumped donated milk for their patients and asked one mother to give milk to another's baby, and breastfeeding support groups have stored milk in home freezers (often referred to as "kitchen banking") to give to babies in need in and out of hospitals, all without any reported untoward incident. However, with the current issues related primarily to viral transmission in any donor tissue, HMBANA member banks see careful screening and processing of donor milk as imperative for protection of the recipients. We also see collaboration with the FDA as potentially the most effective way to assure uniform standards as the use of donor milk increases. Although HMBANA's first collaborations with the FDA were with the Clinical Nutrition Branch, donor milk is a tissue with unique properties and belongs more with tissue banking, than with special formulas. The purpose is to provide a safe human tissue, which happens to also be primary nutrition for most recipients. The milk is not formulated in any way.