House Amendments to Senate Amendment to H.R. 2764 – State, Foreign Operations, and Related Programs Appropriations Act, 2008 (Consolidated Appropriations Act, 2008)

Joint Explanatory Statement to Accompany Consolidated Appropriations Amendment

DIVISION A-AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS ACT, 2008

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Congress passed, and the President signed, the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDAAA placed a cap on the number of waivers that can be issued annually and reduced them by 25 percent over the life of the Act. The Committees note that the waiver limits passed in FDAAA were less stringent than those proposed by FDA in March 2007. The Committees remind FDA that the FDAAA limitations are a ceiling and strongly encourage FDA to continue its efforts to limit the use of financial conflicts of interest waivers to greatest extent possible.

The Committees note that on December 28, 2007, the Center for Veterinary Medicine issued a draft risk assessment on animal cloning which concluded that food products from cloned animals are safe to enter the food supply. During the public comment period, thousands of submissions were received by FDA. Many of these asked the FDA to obtain more information not assessed in the initial risk assessment, including further evaluation of the potential health, economic, and trade impacts, before acting further. In addition, many comments expressed concern that several of the studies on which the risk assessment was based did not undergo a scientific peer review process. The Committees strongly encourage FDA to continue the voluntary moratorium on introducing food products from cloned animals into commerce until FDA completes a review and analysis of
comments and evaluates the need for additional studies recommended during the public comment period.

The Committees direct the Food and Drug Administration to enter into an agreement with the Economic Research Service at USDA to study the domestic agricultural and international trade economic implications of permitting commercialization of milk and meat from cloned animals and their progeny into the food supply.

The amended bill includes $1,725,000 for research on dietary supplements at the National Center for Natural Products Research in Oxford, Mississippi; $149,000 for the Interstate Shellfish Sanitation Commission (ISSC) and $186,000 for ISSC Vibrio Vulpificus; $74,000 for the Warehousing Education and Research Council; $2,228,000 for the National Center for Food Safety and Technology; $1,769,000 for the Food Technology Evaluation Laboratory at New Mexico State University; and $563,000 for collaborative drug safety research with the Critical Path Institute and the University of Utah.

The Committees are aware, and appreciate, that FDA is currently working to update the format of its Explanatory Notes in an attempt to streamline information provided and make it more useful to Congress. The Committees direct FDA to ensure that all changes to the Explanatory Notes reflect the comments made by the Congress.