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November 14, 2011

Dr. Margaret Hamburg
Commissioner, Food and Drug Administration
WO Bldg 1 Rm. 2217
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

Keep Antibiotics Working (KAW), a coalition of public health, consumer, environmental and other groups representing more than 11 million supporters, is deeply disappointed by the Food and Drug Administration's (FDA) recent denial of an important citizens' petition. The 2005 citizens' petition called for the FDA to begin withdrawing the approval of the non-therapeutic uses of seven classes of medically important antibiotics because these uses were inconsistent with FDA's standards of safety with respect to antibiotic resistance. KAW member groups were involved in drafting the 2005 petition (Original Docket No. 05P-0139/CP). When we met early in 2009, you described the problem of antibiotic resistance as an urgent priority. However, since then we have seen the FDA consistently moving away from any decisive action to address the problem.

In denying the petitions, the FDA did not challenge the public health imperative to reduce antibiotic use. Instead the FDA has argued that its own formal process for withdrawal of its market approval for such drugs – with authority granted the Agency by Congress under the Federal Food, Drugs, and Cosmetic Act – is too expensive and resource intensive. As stated in the FDA's denial letter, the Agency instead has embarked upon a plan "to work with sponsors who approach FDA and are interested in working cooperatively with the Agency."

The FDA's mandate to protect public health, in other words, is on hold while the Agency waits for regulated pharmaceutical companies to voluntarily reduce sales of their own products, working against their own financial self-interest. There is absolutely no reason to believe the pharmaceutical companies will do so. And yet reducing antibiotic overuse is essential for making sure antibiotics will keep working for years to come. Without achieving such reductions, the FDA is unlikely to realize any public health benefits.

For this reason we fail to recognize how the FDA's current course of action is a satisfactory answer either to the petition or to the FDA's public health mandate to address antibiotic resistance. Rather, the current approach is counterproductive as it takes up FDA staff time and other resources that could be better used to begin formal withdrawal proceedings. Furthermore, the FDA has not sought additional resources from Congress nor has it supported legislation, namely the Preservation of Antibiotics for Medical Treatment Act, aimed at easing the FDA's burden in addressing the problem.

We hope the FDA will fulfil its mandate of protecting public health and implement regulatory action to end a practice that we all have recognized as endangering the viability of these miracle drugs.

Sincerely,



Richard Wood
Steering Committee Chair
Keep Antibiotics Working

cc: Deputy Commissioner Michael R. Taylor, JD
Director Bernadette M. Dunham, DVM, PhD