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January 17, 2008

The Honorable Andrew von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the use of the chemical bisphenol A (BPA), particularly in products intended for use by infants and children.

It has come to our attention that BPA may be used to coat the lining of cans used to store infant formula and that BPA from this lining may leach into the formula itself, thereby exposing babies to BPA. According to a November 20, 2007, statement (attached), FDA recently completed a review of bisphenol A and found that the reviewed studies "do not indicate a safety concern at the current exposure level for infants or adults" and that "FDA sees no reason at this time to ban or otherwise restrict uses now authorized." In addition, the statement indicates that a dietary exposure of 3.7 parts per billion in certain canned foods and baby bottles measured by FDA scientists does not warrant regulatory action.

Therefore, we ask that you please respond to the following questions and requests:

1. Which specific office or division within FDA has the responsibility for determining the agency's policy on BPA, and who is currently in charge of that office?

2. On what studies is FDA basing the claim that there is no "safety concern at the current exposure level"? If FDA is relying on published studies, please provide us with the scientific citations from any studies used by FDA in making this determination.

3. Please provide the Committee with a summary of any tests that FDA scientists have conducted to determine levels of BPA in canned food or migrating from baby bottles. Indicate for each test the specific product tested, the methodology used (e.g., gas chromatography-mass spectrometry, liquid chromatography-mass spectrometry, high performance liquid chromatography, or enzyme-linked immunosorbent assay, etc.), as well as the detection limit for the assay used.

4. Please provide all records relating to BPA that FDA employees and consultants have produced since 1998.

Copies of the requested records should be delivered to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Room 316, Ford House Office Building, no later than two weeks from the date of this letter. Please note that for the purpose of responding to this request, the terms "record" and "relating" should be interpreted in accordance with the attachment to this letter. After review of the records, we may require additional records and/or FDA staff interviews.

Thank you for your prompt attention to this matter. If you have any questions related to this request, please contact us or have your staff contact John F. Sopko or Paul Jung with the Committee staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

FOX 5

FDA Statement on Bisphenol-A and Microwaving Food

Last Edited: Tuesday, 20 Nov 2007, 7:26 PM EST
Created: Tuesday, 20 Nov 2007, 7:26 PM EST

The FDA issued this statement on the safety of bisphenol-A and also the effect of microwaving food in plastic containers.

The **Food and Drug Administration (FDA)** is actively reviewing the safety of bisphenol-A. FDA has recently completed a review of the available pharmacokinetic data and several animal studies, including two recently completed multigeneration reproductive studies (one in the rat and one in the mouse).

These multigeneration reproductive studies, which were completed per regulatory guidelines and included some developmental endpoints as well as a wide range of doses, do not indicate a safety concern at the current exposure level for infants or adults. We will continue to monitor data on BPA to determine if a safety concern exists. If such a concern exists, FDA will take the appropriate post-market regulatory action.

Considering all the evidence, including the very low dietary exposure to BPA (3.7 ppb) based on measurements by FDA chemists of levels found in canned foods or migrating from baby bottles, and the fact that bisphenol-A has not demonstrated adverse effects when consumed by animals in amounts far higher (orders of magnitude) than humans would consume, FDA sees no reason at this time to ban or otherwise restrict the uses now authorized.

FDA is aware of several reports stating that BPA has estrogen-like activity. However, there are other reports that appear to dispute any reason to expect harm at the low exposures that humans experience. A March 2007 report from a consumer group included studies showing the levels of BPA found in canned foods and migrating out of PC baby bottles and included claims that these levels are unsafe.

FDA scientists have reviewed the available information from this report and have concluded that the BPA levels found in canned foods or migrating out of PC baby bottles are not significantly different than the very low levels previously found by FDA chemists and other laboratories, levels that result in a dietary exposure that is orders of magnitude below the levels known to not cause toxic effects in animals.

FDA POSITION ON MICROWAVING FOOD

FDA evaluates plastics for their safety in contact with food by extracting them with simulating solvents at temperatures representative of use temperatures. The most important variables are food type (aqueous, fatty or dry), temperature and time. Approvals would not be specific to microwaves but may specify holding food during cooking. Generally, microwave cooking takes less time and the highest temperature reached would be the temperature of the food, boiling water being the highest except, possibly, microwave popcorn. Water and a fat stimulant would be used to extract the plastic as measurements can be more sensitive in the absence of a complex food matrix.

Estimates are made of a person's daily intake based on how much food is likely to contact the plastic, and how much substance is extracted into the simulating solvents. As the estimated intake increases, the requirements for toxicity testing increase. A safety factor is applied to ensure that human intake is far below amounts that have no effect on laboratory animals (at least 100 times lower and sometimes 1000 or more times lower, depending on the specific animal tests.

Amounts of packaging getting into food will always be far below levels that could have acute effects but are geared to look for effects from lifetime consumption. Toxicity data required range from a low of a general profile for minor exposure to 90 testing in two species and up to lifetime animal testing in two species. The 100 fold safety factor is used when lifetime data are available.