NATIONAL CHICKEN COUNCIL
1015 15th Street, NW, Suite 930
Washington, DC 20005
Telephone: 202-296-2622 ext. 113

U.S. Poultry & Egg ASSOCIATION
1530 Cooledge Road
Tucker, GA 30084
Telephone: 770-493-9401

August 29, 2011

Margaret Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Hamburg:

The U.S. Poultry & Egg Association (USPOULTRY) is the world's largest poultry organization. USPOULTRY is a nonprofit organization which represents its poultry and egg members through research, education, communications and technical services. Membership includes producers and processors of broilers, turkeys, ducks, eggs and breeding stock, as well as allied companies. We have member companies worldwide and 27 affiliated state associations.

The National Chicken Council (NCC) is a nonprofit member organization representing companies that produce and process over 95 percent of the broiler/fryer chickens marketed in the United States. NCC promotes the production, marketing and consumption of safe, wholesome and nutritious chicken products both domestically and internationally. NCC serves as an advocate on behalf of its members with regard to the development and implementation of federal and state programs and regulations that affect the chicken industry.

USPOULTRY and NCC are writing to share our concerns about the recent suspension of sale of roxarsone animal drug products. In particular, we are concerned that the withdrawal of roxarsone products from the marketplace was not based upon adequate scientific study. We also want to bring to the agency's attention the numerous unintended consequences that are likely to result from the withdrawal of roxarsone products from the marketplace, which include an increased risk of foodborne illness, increased costs due to the need for additional feed, and detrimental environmental impacts resulting from the use of more feed.

The announcement that Alpharma, a Pfizer subsidiary, would suspend U.S. sales of roxarsone followed FDA's completion of a study of 100 broiler chickens to assess the levels of inorganic arsenic in the chickens' livers. This study was extremely limited in scale and also was not peer reviewed. It involved newly developed analytical techniques, included extremely long sample storage periods, and utilized a feed formulation atypical of commercial poultry feed. We are concerned that Pfizer's withdrawal of roxarsone (which likely was a result of pressure from FDA) was based only on this single, limited study. Just as FDA never would consider basing a product approval decision on a study with parameters like those listed above, such a study should not have formed the basis for the agency to urge Pfizer to suspend sales of this product. Roxarsone has been utilized safely in the industry for seven decades and its sale should not be withdrawn based only on this single, limited, non-peer reviewed study.

There are significant potential consequences associated with the withdrawal of this product from the market place. A study performed by Schering-Plough Animal Health in 2003 indicated that the increased health of the bird's intestinal tract, resulting from the use of roxarsone, increased the strength of the chicken's intestine. A weaker intestinal tract can increase the possibility of intestinal breakage during processing. This, in turn, could increase contamination of the carcass with contents of the digestive tract. In short, although the withdrawal of sale of roxarsone was intended to avoid a hypothetical concern about arsenic, in reality this action opens the door to a more tangible possibility – an increase in food borne illnesses due to intestinal breakage during processing.

For over 60 years, arsenicals have been used to control the parasitic coccidia, especially *Eimeria tenella*, to enhance the health of the chicken's intestinal tract. Research studies have shown control of these coccidia increases the bird's ability to absorb feedstuffs and improve a chicken's feed conversion ratio. This means that a chicken fed roxarsone will retain more of what it eats and gain weight more efficiently as compared to a chicken not fed roxarsone. Pfizer's withdrawal of roxarsone from the market at FDA's request will translate into the need for an additional 675,000 tons of poultry feed per year. In turn, this will have two additional effects. First, particularly with respect to corn, it will exacerbate an already precarious world grain supply situation. Secondly, the environmental footprint of poultry production will increase because of the poultry industry's need for additional grain supplies as a result of this action.

Approximately 675,000 tons of additional poultry feed will be required with the loss of roxarsone from the market. With an approximate composition of 68.5% corn and 21.9% soybean meal, this will require an additional 462,000 tons of corn and 148,000 tons of soybean meal. USDA recently projected year–end stocks of corn to dip to a record low of 12,750,000 tons. The additional 462,000 tons of corn required for poultry feed as a result of the roxarsone withdrawal represents almost 4% of year-end stocks! Given the extremely tight world grain supplies, the withdrawal of roxarsone has the potential to not only further accelerate recent world grain price surges, but also limit availability of agricultural products around the world.

The roxarsone withdrawal will have adverse environmental consequences as well. Based on the average yield per acre, an additional 105,140 acres and 78,809 acres would be needed to grow the additional corn and soybeans, respectively. Furthermore, energy will be required during each step in the feed manufacturing process. An evaluation of the additional energy that will be required to harvest the corn and soybean crop is summarized in the following table.

**Estimated Energy Requirements for Additional Corn and Soy Meal Production**

| Fuel Type | Amount Required | |
|---|---|---|
| **Gasoline:** | **316,920** | **Gallons per Year** |
| **Diesel Fuel:** | **1,038,800** | **Gallons per Year** |
| **LP Gas:** | **897,950** | **Gallons per Year** |
| **Natural Gas:** | **71,483,500** | **SCF per Year** |
| **Electricity:** | **7,747,000** | **kWh per Year** |

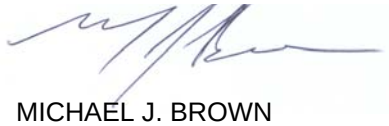
In addition to the increased energy requirements, there will be a significant increase in the emission of pollutants into the atmosphere. The increased emissions will be generated on the farm during the cultivation and growing process, during the feed mill production process and from the transport of raw and finished materials by rail and truck. The table below provides a summary of the additional emissions that will be generated from the production associated with 675,000 tons of feed.

**Estimated Additional Air Emissions**

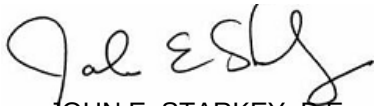
| Constituent | Amount Released from Feed Mills (Ton/year) | Amount Released from Transportation (Ton/year) | Amount Released from Farming (Ton/year) |
|---|---|---|---|
| **Nitrogen Oxides** | **20.2** | **255** | **450** |
| **Particulate Matter** | **56.5** | **4,000** | **1,080** |
| **Sulfur Dioxides** | **32.7** | **13** | **-** |
| **Volatile Organic Compounds** | **0.2** | **37** | **-** |
| **Carbon Monoxide** | **3.3** | **367** | **-** |

Beyond the unintended consequences of this action, we are particularly concerned with the manner in which the withdrawal decision was reached. After seven decades of safe usage by billions of chickens with no evidence of any carcinogenic or other adverse health effect, a non-peer reviewed study of 100 chickens has resulted in the loss of a valuable tool for the maintenance of poultry health. The collateral impacts of this action are sobering for anyone interested in maintaining U.S. agricultural competitiveness and for our ability to produce safe, healthy, affordable food products for the world. While the poultry industry would support the removal of roxarsone from the market if the decision was warranted by a complete and accurate pool of research, the single study conducted by FDA does not meet that benchmark. Pending further study, we urge the FDA to reverse its conclusion regarding roxarsone and request that the Agency withdraw its directive requesting that Pfizer remove this product from the market.

Sincerely,



MICHAEL J. BROWN
President
National Chicken Council



JOHN E. STARKEY, P.E.
President
U.S. Poultry & Egg Association