

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:)
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) FDA DOCKET: 00N-1571
) DATE: December 9, 2002
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Enrofloxacin for Poultry: Withdrawal)
of Approval of Bayer Corporation's)
New Animal Drug Application)
(NADA) 140-828 (Baytril))
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Written Direct Testimony of Kenneth M. Koziol

1. My name is Kenneth Koziol, and I am Vice President for Worldwide Quality Assurance at the McDonald's Corporation (McDonald's). In this capacity, I lead the worldwide development of policy and practices for quality, food safety and social responsibility in McDonald's supply chain. I have worked at McDonald's since 1982 and have been in my current position since 2000.

2. I am pleased to respond to the Food and Drug Administration's request for information about McDonald's decision to cease purchasing poultry meat from birds treated with fluoroquinolones for our U.S. restaurants.

For scientific expertise on issues related to food safety, human health, and animal welfare, McDonald's typically consult with FDA, other federal agencies, international organizations, academic and other independent experts, and the veterinary and microbiological staff at our key suppliers.

In our exchanges with federal agencies, our principal contribution is not scientific. What we offer is information about food industry operations and the potential impact of agency decisions. As a global brand and food safety leader, with a worldwide network of local suppliers, quality and safety facilities, managers, and franchisees, we have a wealth of data and practical experience. We have welcomed opportunities to share them with FDA, other government agencies, and organizations in the private sector, including other restaurant companies. We share because, on matters of food safety and consumer protection, it is the right thing to do and because, in the long run, sharing benefits the entire industry.

McDonald's strongly supports deliberative, consultative rulemaking processes, internally and by government agencies. We commend FDA for following the formal administrative hearing process here. Decisions based on sound science and a practical understanding of real-world impacts are most likely to emerge from a process that affords all interested parties an opportunity for input.

3. The McDonald's Corporation is the world's largest franchise operation. The system comprises approximately 29,000 quick service restaurants in 121 countries. In the United States, we have nearly 12,000 traditional restaurants, plus approximately 1,000 satellite installations in facilities like Wal-Marts and hospitals. There are McDonald's restaurants in every state and the District of Columbia.

4. Everything our restaurants use and serve comes from independent suppliers who produce for us according to our specifications. Many of them are long-time partners with whom we work closely to ensure the highest possible standards of food safety and quality. For us, there is no higher priority, and our belief is that the best way to ensure this is through an ongoing and constructive dialogue with many stakeholders, including industry.

5. McDonald's is one of the world's largest purchasers of poultry meat. Last year, in the U.S. alone, we purchased over 441 million pounds of poultry meat. Worldwide, our 2001 food and paper product purchases totaled nearly \$14 billion. Though our shopping cart is much bigger than the typical consumer's, our purchases are still a small fraction of the total market. If we influence food industry standards and methods of operation—and we do—it is through collaboration with our suppliers, leadership, and information sharing, not the raw muscle of purchasing power.

6. We believe we have an obligation to act as a positive force for social responsibility. We also recognize that hasty unilateral action could cause disruptions in agriculture and food processing industries. So when we consider a change in our procurement standards, we take great care to ensure that it is based on sound science and, to the best of our understanding, the right thing to do. We also consult with our suppliers, their trade associations, regulatory agencies, and others who can provide insight into the desirability and feasibility of the change. We seek, so far as possible, to develop a consensus on a course of action. This is the process we followed when we led the industry in eliminating the use of polystyrene containers, in recycling, certification for compliance with FDA's ruminant feed rules, and our global animal welfare guidelines. It is also the process we followed in developing our policy on antibiotics.

7. The trigger for our non-fluoroquinolone standard was an article in the *Washington Post*. Our technical staff had been following the research on uses of antibiotics in animal agriculture, and there was already discussion within the company about reducing uses within our supply chain. Thus, there was already a familiarity with the general issues. In the case of fluoroquinolones, we decided to move ahead.

We conferred with our U.S. poultry suppliers, Keystone Foods LLC and Tyson Foods, Inc. We learned that Keystone had ceased using fluoroquinolones in broilers some time ago. Tyson volunteered to stop using the drugs if that was what we wished. We also conferred with the scientific experts at Keystone and Tyson, with our own technical staff, and with our Global Quality Assurance Board, a panel of representatives responsible for food safety and quality. The U.S. team concluded that considerable evidence supported serious concerns about fluoroquinolones and that eliminating them from our supply chain in the U.S. would not be disruptive.

On this basis, we established an agreement with our suppliers that fluoroquinolones would not be used. We did leave open the possibility that they might be used in some catastrophic and unforeseen emergency, since they remain an approved medication. Our prior approval is required before this could happen. Our policy has been in place formally for two years without a request to use fluoroquinolones. In fact, it has been more than three years since the last time fluoroquinolones were used on any poultry we have purchased.

8. As a socially responsible company, McDonald's knows that our responsibility to stakeholders goes beyond our P&L (profits and loss) statement. We have in the past chosen to do the right thing knowing it would increase our costs and will undoubtedly do so again. However, our decision on fluoroquinolones has thus far had little impact on the bottom line. Nor, so far as we know, has there been any notable cost impact on our suppliers. However, that the decision has been in force for only 18 months or so. Whether these cost impact indicators hold up in the long run remains to be seen.

9. As the foregoing indicates, McDonald's supply chain will not be affected by the withdrawal of fluoroquinolone use in poultry that the Center for Veterinary Medicine proposes because we have already voluntarily adopted a fluoroquinolone ban. We are nevertheless interested in these proceedings. Formal administrative processes are important to the entire business community. They contribute to stability, transparency, and participation agency decision-making. They help ensure consideration of diverse views. When an agency follows the administrative process, it reinforces confidence in the system. Businesses need that—as, indeed, does the general public. So, again, McDonald's commends FDA for following the formal administrative process in this instance and more generally.

10. As a good citizen, we care about the health of the American public. We believe the human health risks posed by the use of fluoroquinolones in poultry are serious and supported by sound science. We also believe the proposed withdrawal of fluoroquinolones from use in poultry will help maintain consumer confidence in the safety and wholesomeness of the U.S. food supply. This is, in our view, the preeminent mission of the federal food safety agencies. The strength of the U.S. food industry, including our business, depends on their fulfilling this mission judiciously and aggressively.

11. There has been no change in the quality, taste, price or consumer acceptance of our chicken products (chicken patties, McNuggets, and chicken salads) in the more than three years since we have been using fluoroquinolone-free chicken.

12. McDonald's, therefore, supports the proposed withdrawal of the use of fluoroquinolones in poultry and appreciates this opportunity to contribute to the deliberative process FDA is so rightly following.

I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct.

Kenneth M. Koziol

(Date)