David W. Blois, Ph.D.
Senior Vice President
Global Regulatory Policy

Merck & Co., Inc.
West Point PA 19486
E-Mail: david_blois@merck.com
Tel 484 344 2304
215 652 5000
Fax 484 344 2335

August 26, 2003

MERCK
Research Laboratories

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

RE: Docket No. 03N-0168
Current Status of Useful Written Prescription Drug Information for Consumers

Merck & Co., Inc. is a leading worldwide human health product company. Merck's corporate strategy — to discover new medicines through breakthrough research — encourages us to spend nearly $3 billion annually on worldwide Research and Development (R&D). Through a combination of the best science and state-of-the-art medicine, Merck's R&D pipeline has produced many of the important pharmaceutical and biological products on the market today.

Merck supports the dissemination of useful written prescription drug information to consumers (also known as Consumer Medication Information [CMI]) as an important tool through which to improve patient compliance, avoid preventable medication errors, and improve health outcomes. Merck is interested in what steps can be taken to improve the usefulness and distribution of written prescription drug information in order to meet the 2006 goal of Public Law 104-180. We provide general comments followed by our comments on the four questions on which FDA is soliciting input.

GENERAL COMMENTS

Merck recommends that the Agency focus its current efforts on gaining a better understanding of how third parties generate written prescription drug information and how the information is distributed to consumers. The current system appears deficient in both aspects; thus, a comprehensive review of the process is needed if an effective solution is to be implemented. To date, voluntary private sector efforts have failed to meet the goals of PL 104-180, which may not be surprising given that the "pharmacy industry[1]" appears to lack an integrated approach through which to meet usefulness and distribution goals and also appears to lack sufficient incentives to invest in systems and processes to achieve those goals.

[1] "Pharmacy industry" is defined as generators of CMI (e.g. First DataBank), data vendors, software vendors, and pharmacists.

Merck maintains that the pharmaceutical manufacturer and FDA are the primary sources and best sources of current, scientifically accurate information about medicines. Both the manufacturers and the FDA have incentives to provide quality information about prescription drugs to consumers, and as such, are keenly interested in information generation and distribution. This is evidenced in the pharmaceutical industry where there are many routes through which consumers receive information about their medicines such as package inserts (PIs), patient package inserts (PPIs), Medication Guides, direct-to-consumer advertisements, educational brochures, toll free telephone lines, and product websites. This is evidenced at the Agency through the "Consumer Drug Information" page on the Agency's website, and the review and approval of PPIs and Medication Guides.

Merck believes that additional oversight of the written information produced by third parties about prescription drugs is critical to ensure overall quality. The Agency currently does a very good job reviewing information generated by the pharmaceutical industry so that it is consistent with the data contained in approved marketing applications and across classes of drugs. We suggest that the voluntary system currently in place could benefit from FDA's expertise with the content of consumer-directed medication information via the issuance of guidelines (such as *Points to Consider in the Production of CMI*) and by taking advantage of the product knowledge available from the pharmaceutical industry.

The more difficult aspect of the current system can be described as "flaws in the distribution chain" whereby quality CMI does not reach patients. This is a much more difficult area to address as there are many stakeholders, each with unique roles and problems. Therefore, we recommend that the standards for CMI use and distribution be addressed at a national level, recognizing the role that state Boards of Pharmacy must play. The National Association of Boards of Pharmacy (NABP) can respectfully acknowledge the FDA guidelines on CMI content while setting standards for CMI use and distribution thereby influencing generators of CMI (e.g. First DataBank), data vendors, and software vendors, to provide products that meet the needs of patients and that are practical for pharmacists.

FDA QUESTIONS

1. **What steps is the private sector taking to improve the usefulness of the written information patients receive with prescription drugs and to meet the Year 2006 goal?**

To date, Merck has produced 10 FDA-approved PPIs. In the future, we intend to produce PPIs for select new products as they are approved.

Merck has increased the packaging of its products in the unit-of-use form so that PPIs, where available, are included in each package received by the consumer, assuming that the pharmacy dispenses the product in the unit-of-use form.

Merck has posted PIs, PPIs, and other educational information on our company website (www.merck.com) and, where available, on product-specific websites, to make the information readily accessible to consumers and other interested parties. This information is updated and maintained to reflect the most current FDA-approved labeling.

2. What barriers exist for the private sector to meet the Year 2006 goal, and what plans exist to overcome these barriers?

The current system fails in one respect in that FDA-approved, company-generated PPIs, where available, are not distributed to consumers. Because they are FDA-approved, these PPIs are the best sources of current information about prescription drugs. Minimally, we would like to see PPIs, where available, be distributed as the preferred CMI in the pharmacy.

The current system fails in another respect in that the parties that generate written summaries of prescription drug information utilize independent research and alternative sources of information and do not avail themselves of the best and most current information available from the pharmaceutical industry and the FDA to ensure that CMI reflects the currently approved product information. We encourage producers of written information (e.g. First DataBank and Medi-Span) to avail themselves of the information provided in the PIs and by the Medical Information Services of pharmaceutical companies and information available on the FDA website as a first step to improving the accuracy and completeness of CMI.

Lastly, the current system fails in that pharmacies may modify CMI, developed and distributed by third parties (e.g. First DataBank and MediSpan), thereby removing information valuable for consumer education. We understand that this happens because of logistical considerations. While we appreciate that business practices vary widely, this practice cannot be allowed to continue, if "usefulness" criteria are to be met by the year 2006. We encourage the pharmacy trade and professional associations, state Boards of Pharmacy, and the Agency to develop educational campaigns to discourage this practice and to encourage adherence to standards for CMI use, as developed at the national level and via FDA guidelines.

3. What should the role of FDA be in assuring full implementation of the Action Plan to meet the Year 2006 goal?

We recommend that the Agency issue guidelines or Points to Consider to:

- reiterate the Keystone criteria for content and usefulness
- include formatting suggestions (e.g. Question and Answer, bullets, headers, spacing)
- provide examples of CMI that meet and do NOT meet the Agency's expectations
- describe how to develop CMI from the FDA-approved PI
- recommend how to handle CMI when the FDA-approved PPI exists
- address off-label uses

We suggest that FDA evaluate to what extent the mail order pharmacy business will contribute to goals for 2006; mail order pharmacy is a growing vehicle through which consumers fill prescriptions. Are there unique aspects of mail order pharmacy that differ from local pharmacy?

We suggest that FDA give thought to how the generic pharmaceutical industry could contribute to the dissemination of PPIs; an increasing number of outpatient prescriptions are filled with generics. Is the generic industry merely reliant on copying innovators' PPIs, when they exist? What happens when the innovator ceases to manufacture its product? Or does not produce a PPI?

4. **What other initiatives should FDA consider for providing patients with useful written information about prescription drugs as endorsed by Public Law 104-180? Such initiatives include the possibility of FDA requiring manufacturers to provide authorized dispensers with the means to distribute useful written information approved by FDA.**

In addition to the guidelines mentioned in Answer 3 above, it is important for the Agency to look toward the use of electronic labeling, including PPIs, to move away from including outdated paperwork (e.g. PPIs and PIs) in packages. This could be accomplished through regulatory reform to modify the requirement that the PPI and PI be contained in the package as shipped from manufacturer, and by providing for an electronic distribution system. PhRMA's Paperless Labeling Initiative has the advantage of making PIs and PPIs widely available in electronic format. Thus, healthcare providers will always have most current versions of these documents on hand ensuring that PPIs can be viewed, printed, and distributed at multiple places where consumers receive medication and advice, and use medication (e.g. pharmacy, doctor's office, hospital, clinic, mail order, home).

The Agency should continue to approve PPIs submitted by the pharmaceutical industry and dedicate resources to their timely review, perhaps under the Agency's risk management initiatives.

CONCLUSIONS

We acknowledge the complexities of the current system through which the private sector creates and distributes written information about prescription drugs, and the difficulties faced by the Agency while attempting to improve the system so that 2006 year goals are met. We recommend that the Agency issue CMI guidelines or Points to Consider and evaluate and encourage the activities described below.

Evaluate

1. how third parties generate written prescription drug information and how the information is distributed to consumers in order to integrate the approach
2. how state Boards of Pharmacy or NABP oversee CMI
3. to what extent the mail order pharmacy business contributes to 2006 goals

4. the role of the generic pharmaceutical industry
5. how the Agency can move quickly toward the use of electronic PIs and PPIs

Encourage

1. establishment of CMI standards at the national level
2. additional oversight of the written information produced about prescription drugs to ensure overall quality
3. utilization by third party producers of written information of the FDA-approved labeling and other information available from the pharmaceutical companies to improve the accuracy and completeness of CMI

We appreciate the opportunity to comment on the topic of CMI and are available to meet with you to discuss these issues.

Sincerely,

Lauren M. Hetrick

for David Blois, Ph.D.
Senior Vice President
Global Regulatory Policy