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MERCK

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515-6115

The Honorable Bart Stupak
Chairman
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
United States House of Representatives
Washington, DC 20515-6115

Dear Chairman Dingell and Chairman Stupak:

Thank you for your letter of May 20 seeking information on Merck & Co., Inc. policies on broadcast direct to consumer (DTC) advertising. Merck conducts broadcast DTC advertising as part of a comprehensive program to inform physicians, other prescribers, patients and care givers on the benefits and risks of our medicines and vaccines. Our policies and our commitment to full compliance with all applicable laws, including the regulations, policies and guidelines of the Food and Drug Administration, require us to ensure that, at all times, our information is balanced and consistent with the FDA-approved labeling of our medicines and vaccines.

Currently, Merck uses product-specific broadcast DTC advertising for two of our pharmaceutical products – SINGULAIR and JANUVIA – as well as for our vaccine, GARDASIL. My responses to your questions relate to our policies and to these advertisements. We also use broadcast DTC advertising in connection with our joint venture with the Schering-Plough Co. Responses to your questions related to that joint venture will come to you from the joint venture. I have reviewed those responses and agree with them.

To facilitate our responses, this letter presents both your questions and Merck's responses to each.

1. Follow the American Medical Association's guidelines regarding the use of actors and health professionals in DTC advertisements.

None of Merck's current product broadcast DTC advertising presents health professionals or actors portraying health professionals. If, in the future, Merck does present a health professional or an actor portraying a health professional, we intend to respect sections 1(h) and (i) of the American Medical Association's policy (H-105.988 Direct-to-Consumer (DTC) Advertising of Prescription Drugs and Implantable Devices) regarding the use of actors and health professionals in product-specific DTC advertisements. Specifically, we will identify instances in which an actor is portraying a physician. In addition, if our product advertisements include a physician, we will identify that the physician has been compensated for appearing in the advertisement.

2. To not market products in DTC advertisements until a valid outcomes study of the product is completed and results are released.

Our current broadcast DTC advertising and future advertising is based on FDA-approved labeling for our medicines and vaccines that may include statements derived from outcomes studies or statements that come from studies of validated surrogate measures. As you know, the FDA approves the use of medicines and vaccines based both on outcomes data and on well-studied surrogate measures. This is important to ensure patients have timely access to medicines and vaccines. Merck will continue to follow FDA regulations and guidance regarding DTC advertisements, including any recommendation to include a specific disclaimer in DTC advertising relating to whether clinical outcomes have been demonstrated for a particular product.

3. Place a two-year DTC advertisement moratorium on new prescription drug products, as recommended by the Institute of Medicine.

Merck has allowed an appropriate period of time between the approval of a new product and the start of broadcast DTC advertising. In deciding when to initiate advertising for a new product, Merck considers both the need for physicians and other prescribers to have sufficient information to engage in an informed discussion with their patients and the need for patients to get timely information on the availability of new treatment options. Merck takes steps to educate physicians about a new product before commencing product-specific DTC broadcast advertising. This is consistent with the PhRMA Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines that state that companies should spend an appropriate amount of time to educate health professionals about a new medicine before beginning a DTC campaign.

Our current practice often results in a six month period between the date of product approval and the commencement of a DTC broadcast campaign for a new product. Therefore, going forward we are committing to a minimum six month time period following the approval of a new product before beginning DTC broadcast advertising.

Notwithstanding this commitment, Merck continues to believe that the precise period of time will vary by product and that specific products may support a longer period of time before the commencement of DTC broadcast advertising. As a result, we will continue to educate health care professionals about a new medicine or vaccine and to evaluate awareness of physicians in determining the appropriate time to initiate DTC broadcast advertising following that six-month period.

4. To not market off-label uses for prescription products in DTC advertisements.

In accordance with the law, FDA regulations and the "PhRMA Guiding Principles – Direct to Consumer Advertisements About Prescription Medicine," Merck broadcast DTC advertising is accurate and not misleading, makes claims only when supported by substantial evidence, reflects a balance between risks and benefits, and is consistent with FDA approved labeling. Advertising an "off-label use" for a medicine or vaccine would be entirely inconsistent with these standards.

In order to ensure that all Merck broadcast DTC advertising meets these applicable laws and regulations and comply with PhRMA's Principles, we review all proposed broadcast DTC advertising in Merck Medical/Legal boards. Merck's Medical/Legal boards are comprised of Merck physicians and lawyers that review promotional materials prior to use, for the purposes of ensuring scientific and medical accuracy, and compliance with Merck's policies and FDA regulations.

We also submit all new broadcast DTC advertising content to the FDA (DDMAC or Advertising Promotion Labeling Branch (APLB)) for advisory comments prior to issuance. We review and address these comments prior to running the broadcast advertisements.

5. Add the Food and Drug Administration's (FDA) toll-free MedWatch phone number in all your DTC advertisements.

Merck supports providing patients and care givers with easy access to information on the MedWatch system, including information on how to access it through the toll-free number. As you know, section 906 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) requires published DTC advertisements to include this 800 number. We support and comply with this requirement. In addition, we are planning to also include this information on contacting MedWatch in a prominent place on Merck's product-specific websites.

Merck also already includes in its broadcast DTC advertising an 800 number that consumers can call to obtain further information including the FDA-approved patient labeling and physician prescribing information for the advertised medicine or vaccine.

Consumers who call that toll-free number can also report adverse experiences to Merck during that telephone call. Merck submits information regarding adverse experiences on marketed products to the FDA consistent with FDA regulatory reporting requirements.

In terms of including an additional 1-800 number for MedWatch in our broadcast DTC advertising, we are currently considering this in the context of the FDA's ongoing study. Since our DTC broadcast advertising already includes a toll-free number consistent with FDA guidance, it is unclear whether adding another 800 number would be helpful to consumers. As required by the FDAAA, FDA is studying whether this additional information would be helpful to consumers and, if so, how it should be implemented in DTC TV advertisements so as not to detract from other important information. We look forward to FDA making a recommendation on whether such a requirement would benefit patients and how the requirement might be implemented in broadcast advertising. Of course, if the FDA makes such a recommendation, we would implement it.

6. If a product of Merck & Co., Inc., and any joint venture to which Merck & Co., Inc. is a party, is required by FDA to include a "black box" warning in its labeling, will Merck & Co., Inc. and any joint venture to which Merck & Co., Inc. is a party, commit to add these "black box" warnings in DTC ads for any such product?

Merck does not use broadcast DTC advertising for any of our medicines that have a "black box" warning. However, if we ever would consider doing so, Merck would certainly add appropriate information relating to the black box warning, consistent with FDA (DDMAC or APLB) regulations and guidance, to any broadcast DTC advertisement.

Chairman Dingell and Chairman Stupak, I hope that these answers are responsive to your questions. We would be glad to provide you with additional information or clarification to any of the questions if you believe that would be helpful.

Sincerely,