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January 17, 2006

By Facsimile [301-796-9877]
and First-Class Mail

Thomas Abrams, RPh, MBA
Director
Division of Drug Marketing, Advertising, and Communications
10903 New Hampshire Ave.
Bldg 22 Rm 1400
Silver Spring, MD 20993-0002

Re: NDA # 21-286 & 21-532
Benicar® (olmesartan medoximil) Tablets
Benicar HCT® (olmesartan medoximil/hydrochlorothiazide) Tablets)
MACMIS ID # 13421

Dear Mr. Abrams:

On January 6, 2006, the Division of Drug Marketing, Advertising, and Communications (DDMAC) sent a warning letter to Sankyo Pharma Inc. (Sankyo) alleging that a sales aid (SPBN04-0149) for Benicar® (olmesartan medoxomil) Tablets and Benicar HCT® (olmesartan medoxomil and hydrochlorothiazide) Tablets "misbrands the drugs in violation of" 21 U.S.C. § 352(a). We urge DDMAC to withdraw the letter. As discussed below, the letter articulates positions on comparative claims, the disclosure of material facts, and corrective promotion that violate the First Amendment and exceed FDA's statutory authority. We have previously corresponded with DDMAC on each of these issues, requesting that DDMAC conduct a comprehensive review of its policies and procedures to ensure they are consistent with applicable constitutional and statutory limitations. We have received no response to our earlier letters. WLF nevertheless renews its request for such a review.

Untenable Stance on Comparative Claims

DDMAC first contends in its letter to Sankyo that the sales aid's claims that Benicar and Benicar HCT are more effective than other angiotensin II receptor antagonists and their HCTZ combinations are unsubstantiated because the references Sankyo provides in support of these claims "do not constitute substantial evidence or substantial clinical experience."

WLF objected to DDMAC's stance on comparative claims in a letter dated July 27, 2005, regarding Pfizer's promotion of ZYVOX. In that letter, we explained, it is inappropriate for DDMAC to issue warning and untitled letters objecting to comparative claims when DDMAC

has repeatedly promised, and yet has failed to issue, guidance on comparative claims. We explained, further, that DDMAC's position on comparative claims is highly questionable as a matter of First Amendment principles and in view of the FTC's policy of allowing comparative claims based on substantiation that does not meet DDMAC's rigid two-trial standard. Finally, WLF advised, DDMAC's position is invalid for procedural reasons because it has not been the subject of notice-and-comment rulemaking or GGP procedures.

We have not yet received a response from DDMAC to our earlier correspondence on this issue (or on other issues). WLF remains deeply concerned that DDMAC's established, even if unarticulated, policies on comparative claims are depriving health care practitioners and patients of badly needed information on available therapies. As I explained in my testimony at FDA's public meeting on consumer-directed promotion on November 2, 2005, rather than engaging in an elaborate game of "gotcha" with sponsors over technical violations, DDMAC should seek to provide sufficient guidelines, consistent with the First Amendment and the FDCA, to guide the use of comparative claims and other types of promotional statements. It is only by doing so that DDMAC will enable sponsors to fulfill their potential as rich sources of scientific information on prescription drugs.

Untenable Allegations of Omission of Material Facts

DDMAC continues in the present letter its established practice of objecting to the omission of risk information from a promotional piece that actually contains the allegedly missing facts. Here, DDMAC alleges that Sankyo's sales aid failed to include certain risk information from the PI about use of the drugs in pregnancy, in an activated renin-angiotensin system, in renal artery stenosis, and in patients with impaired hepatic function or systemic lupus erythematosus, and about lithium interactions.

DDMAC's allegations are off the mark. In letters dated June 30 and August 26, WLF objected to DDMAC letters alleging that promotional materials had insufficiently disclosed risk information, despite the fact that the materials were accompanied by the PI. Likewise, here, the sales aid for Benicar and Benicar HCT was used in discussions with health care practitioners in conjunction with the full PI, which is precisely regulated by FDA and contains all of the information necessary for the safe and effective use of the drug, including the risk information that DDMAC alleges is missing. The audience for the piece thus had ready access to all of the information that DDMAC alleges is omitted or insufficiently presented.

This is not the first time that we have objected to untenable allegations that a sponsor has failed to disclose material information. By letters dated June 30, July 20, August 25, September 9, and January 16 (Loprox), WLF objected to DDMAC letters that alleged sponsors had failed to disclose risk information without an adequate legal basis. It is apparent that DDMAC has an established practice and policy of treating as unlawful promotional communications that actually include adequate risk information.

Rather than communicating its expectations about the presentation of risk information in promotional pieces case by case through the issuance of warning and untitled letters, DDMAC should provide concrete guidance to industry on this issue. DDMAC should move swiftly to

finalize its brief summary guidance and should also immediately issue for public comment the long-awaited draft guidance on achieving fair balance in promotional materials. The agency, DDMAC, industry, and the public health would be better served by a systematic approach in which all stakeholders have a meaningful opportunity to participate in the development of regulatory norms.

No Authority to Seek Corrective Promotion

DDMAC's request that Sankyo disseminate "corrective" promotional messages because the violations you observe are "serious" is unauthorized by statute, unconstitutional, and imprudent. As WLF previously advised you in our letters of June 30, 2005, the specific listing of enforcement actions appearing in the Federal Food, Drug, and Cosmetic Act conspicuously omits any authority for DDMAC (or any other FDA component) to request or require that a firm disseminate "corrective" promotional messages to anyone. 21 U.S.C. § 331 *et seq.* Moreover, a requirement that a company disseminate information about one of its own products on behalf of the government presents potentially grave First Amendment issues. *See, e.g., International Dairy Foods Ass'n v. Amestoy,* 92 F.3d 67 (2d Cir. 1996).

My testimony on November 2 emphasized the urgent need for DDMAC to reconsider its apparent policy of always requesting corrective messaging in warning letters. Although WLF has consistently presented our views to DDMAC on the inappropriateness of invoking this extra-statutory remedy, we have received no response from you and have seen no lull in the issuance of warning letters invoking it. We again request that you address our concerns in writing and undertake a systematic review of your use of this remedy to ensure it does not exceed your authority and sufficiently respects the First Amendment rights of sponsors and their audiences.

Conclusion and Requested Action

For the reasons discussed above, we request that DDMAC immediately withdraw the warning letter to Sankyo and cease the issuance of warning and untitled letters and advisory correspondence that contain allegations the same as or similar to those described above. We request that you review, in a systematic fashion, all of your policies and procedures to ensure they provide sufficient room for sponsors to disseminate, and health care practitioners and patients to receive, truthful and non-misleading information about prescription drugs. We request, further, that you respond to the numerous legal and policy issues we have raised in our correspondence with you since last year.

The deficiencies described in this letter do not necessarily constitute an exhaustive list. It is DDMAC's responsibility to ensure that its actions with respect to prescription drug promotion, and to other forms of commercial speech, comply with the First Amendment, and do not exceed FDA's statutory authority.

Sincerely,

Richard A. Samp
Chief Counsel

cc: Sheldon Bradshaw (GCF-1)