



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305  
Dockets

MAY 19 2004

Food and Drug Administration  
Rockville MD 20857

0924 '04 MAY 21 10:46

Wayne H. Matelski  
Arent Fox Kintner Plotkin & Kahn  
1050 Connecticut Avenue, N.W.  
Washington, DC 20036

Richard P. Schweitzer, P.L.L.C.  
1776 K Street, NW  
Suite 800  
Washington, DC 20006

Re: Docket No. 00P-1406/PSA1

Dear Mr. Matelski and Mr. Schweitzer:

This responds to your petition for stay of action dated July 14, 2000. For the reasons discussed below, your petition is granted.

You request that FDA stay presenting, conducting, publishing, or otherwise promulgating Fresh Air speeches or documents, and disseminating previous Fresh Air speeches in any form. (FDA's Fresh Air presentations and workshops were intended to provide the Agency's interpretation of how the minimum current good manufacturing practice (CGMP) regulations apply to the manufacturing, filling, transfilling, and cascading of medical gases, both compressed and cryogenic.) You contend, among other things, that under section 405 of the FDA Modernization Act of 1997 (the Modernization Act) and FDA's proposed rule for good guidance practices ("GGPs," now final and codified at 21 CFR 10.115), FDA should formally define the CGMP requirements for medical gases through a guidance document, and publish this guidance document in the *Federal Register* for notice and comment.

FDA is granting your request that we stay presenting, conducting, publishing, or otherwise issuing Fresh Air speeches or documents, or making available previous Fresh Air speeches. As noted in your petition, the last Fresh Air document was a presentation posted on the FDA web site on March 8, 2000, and presented on March 15, 2000. FDA has not made available previous Fresh Air speeches or documents since that time.

FDA is also granting your request that we provide guidance on the CGMP requirements for medical gases through a guidance document, pursuant to section 405 of the Modernization Act and FDA's final rule for GGPs, and publish this guidance document in the *Federal Register* for notice and comment. In the *Federal Register* of May 6, 2003 (68 FR 24005), FDA announced the availability of and requested comments on a draft guidance entitled "Current Good Manufacturing Practice for Medical Gases." Interested persons were given until September 3, 2003, to submit written or electronic comments.

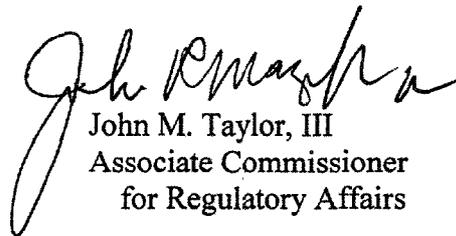
00P-1406

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FDA promulgated CGMP regulations (21 CFR parts 210 and 211) for human drug products on September 29, 1978 (43 FR 45014). In that final rule, FDA stated that parts 210 and 211 are applicable to compressed medical gases unless otherwise noted in the regulations and until other superseding regulations are issued (43 FR 45014 at 45027). At this time, FDA has no plans to issue additional regulations specific to CGMPs for medical gases. FDA is revising the May 6, 2003, draft guidance in response to comments and will issue final guidance to provide recommendations on how to comply with CGMPs for manufacturing, filling, transfilling, cascading, and transferring compressed and cryogenic medical gases.

Sincerely yours,



John M. Taylor, III  
Associate Commissioner  
for Regulatory Affairs