

Better Breathing, Inc.

July 21, 1994

Via: Federal Express

Mr. Richard W. Metzler, Chief
Certification and Quality Assurance Branch
Division of Safety Research
C/O NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C34
4676 Columbia Parkway
Cincinnati, Ohio 45226

Dear Mr. Metzler:

I have examined the first module of the proposed new regulation (42 CFR 84). Representing Better Breathing, Inc., as a manufacturer of NIOSH/MSHA Approved Disposable Particulate Respirators, my comments pertain only to particulate respirators (liquid as well as solid).

I hereby endorse the proposed new regulation which, in my opinion, will; i) enhance the level of protection provided to end-users, ii) update the state of the art in the United States to match that in Western Europe, and, iii) provide more cost effective respiratory protective devices for the healthcare industry.

Having attended the hearings held in Washington, D.C. on June 23, 1994 and listened to various industry, OSHA and healthcare industry representatives, I would like to state Better Breathing's position as well as its state of preparedness to meet the proposed new regulations as follows:

- 1) Better Breathing endorses the classification of respiratory protective devices as proposed: Type A - 99.97%, Type B - 99.00%, Type C - 95%, using a polydispersed and neutralized, cold-nebulized DOP challenge aerosol or an equivalent challenge aerosol.
- 2) Though we have materials and products, in prototype stage, that meet all six categories, namely; A, B, and C in "Solid Only Certification" and in "Liquid and Solid Certification", we recommend that, in the interest of maximum user protection, only the "Liquid and Solid Certification" be adopted. This opinion is based upon the fact that in dental and medical/surgical procedures, aerosols of liquid and solid particulate mixtures are generated. The same is also true, though to a lesser extent, in some industrial settings.

P.O. Box 490
Lawrence, MA 01842-1090
Tel. (508) 794-0297
Fax (508) 794-1465

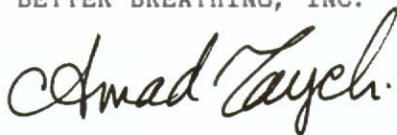
Innovators and manufacturers
of Respiratory Protective Products
for industry, laboratory and
medical uses. JUL 22 1994

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- 3) We will be prepared to submit, for approval, products that meet the new certification levels when the new regulations take effect.
- 4) Though we are presently one of only two producers of NIOSH/MSHA Approved Disposable HEPA Respirators, we believe the new regulation should be adopted in order to provide the financially-struggling (typically not for profit) healthcare industry with high performance cost effective respiratory protective devices for protection of healthcare workers. While we are acutely aware that the industrial segment end-users will incur additional costs as a result of the adoption of the new proposed regulation, we would like to add, in this context, that the new proposed regulations will provide better user protection.

Sincerely,

BETTER BREATHING, INC.



Dr. Amad Tayebi
President

cc: Mr. Richard Metzler, Chief
Certification and Quality Assurance Branch
Division of Safety Research
National Institute of Occupational Safety & Health
1095 Willowdale Road
Morgantown, W. Virginia 26505