

Better Breathing, Inc.

94-371

September 6, 1994

Via Facsimile:
Original Via:

(304) 284-5877
U.S. Mail

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:

Attached, please find a copy of my letter, of even date, to Dr.
Rosenstock.

With best regards, I remain

Sincerely,

BETTER BREATHING, INC.



Dr. Amad Tayebi
President

Attchmt.

DOC. ID\C:\BBI\NIOSH\RM9694

SEP 12 1994

Better Breathing, Inc.

September 6, 1994

Via Facsimile: (202) 205-2207
Original Via: U.S. Mail

Dr. Linda Rosenstock, Director
NIOSH
200 Independence Avenue, S.W.
Room 715H
Washington, D.C. 20201

Dear Dr. Rosenstock:

I am writing in follow-up to my letter, dated July 21, 1994 (copy attached), to the NIOSH Docket in connection with the proposed 42 CFR 84 regulation. In particular, I am writing to emphasize Better Breathing's position regarding Class C Respirators which would meet the CDC and OSHA recommendations for TB applications, as follows:

- 1) In my opinion, the technology for producing disposable Class C Respirators is practical, reasonable and available.
- 2) As a manufacturer of disposable respiratory protective devices, Better Breathing, Inc., is ready to submit for certification, a Class C Respirator, as soon as the new regulation is put into effect and is prepared to market same at a price not exceeding the price of a 30 CFR 11 disposable Dust/Fume/Mist Respirator. Further, we are prepared to offer such respirator with as well as without an exhalation valve without exceeding the proposed exhalation pressure drop limit.

Again, I would like to take this opportunity to endorse the proposed new regulation.

Sincerely,

BETTER BREATHING, INC.



Dr. Amad Tayebi
President

Attchmt.

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Page 1 of 1

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

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.

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

Mr. Richard W. Metzler ,
July 21, 1994
Page 2 of 2.

- 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