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Proposed Regulation on Asbestos Particles in Food and Drugs

The proposed regulation on asbestos particles in food and drugs, described in the Federal Register of September 28, 1973 (21 CFR Parts 121 and 133), has been reviewed and comments are offered.

Page 27077, 3nd Column, 2nd full paragraph.

An additional reference could be included to describe the NIOSH air sampling technique for asbestos: Leidel, NA et al, USPHS/NIOSH Membrane Filter Method for Evaluating Airborne Asbestos Fibers, TR-84, DHEW, PHS, NIOSH, Cincinnati, Ohio. (It is now "in press" and should be published soon.)

Section 121.2006(c).

The polarized light microscope techniques that are presented in this paragraph are very difficult and probably oversimplified in the proposed regulation. It is suggested that the method be referred to in the regulation and in another publication give step-by-step procedures to be followed. This is not accomplished in the reference to the AOAC Methods.

It is doubtful that the recommended technique for dispersing talc on the microscope slide, mentioned in Section 121.2006(c)(2), will provide a uniform particle distribution. It is expected that problems will be encountered when the slide cover is placed over the sample, in that the particles and liquid will tend to be dispersed towards the outer edges of the slide. It is believed more research is needed to ensure obtaining uniform particle dispersion.

Section 121.2006(c)(2)(iii).

The minimum number of slide fields or number of fibers per slide that must be counted must be stipulated so that conversion to fibers per milligram of sample can be calculated. This minimum

number depends on the statistics of uniform distribution of particles determined as in section (3) above. The method for converting from number of fibers counted to the number of fibers per milligram of sample should also be stipulated, as is done in the NIOSH criteria document on asbestos (FDA reference 38) or in the previously mentioned NIOSH TA-84.

Section 133.8(1).

It should be indicated that fiber determinations should be made on the drug samples before and after filter application, since the fibers may be present prior to filter application.

There is no indication of how a "fiber-releasing filter" is found to be so. Is filter counting to be conducted?

A percentage reduction in fiber content should be stipulated, rather than a requirement "...to reduce the content of any asbestos-form particles...".

The reference to the NIOSH criteria document on asbestos for methods to determine asbestos reduction is not sufficient, because the techniques described in that document are for air sampling. Once the fibers are on a millipore filter, subsequent procedures are adequate, but sampling from a liquid medium would be different than sampling from air, and these different sampling procedures should be described.

If the statement that there shall be no fibers released into drugs is meant literally, then the use of phase contrast microscopy, as described in the NIOSH criteria document, is not sufficient. Transmission electron microscopy would have to be used to ensure that no fibers are released. However, the NIOSH analytical procedures are acceptable if you desire to sample for fibers greater than five microns in length.

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