OWENS-CORNING FIBERGLAS CORPORATION

March 12, 1952

Mr. D. L. Yocum, Jr., Purchasing Agent
Abbott Laboratories, Inc.
1200 Sheridan Road
North Chicago, Illinois

Dear Mr. Yocum:

At the suggestion of Mr. E. S. Adams of our General Sales Department I am glad to provide you with information about the propriety of our supplying Fiberglas Aercor (W-300 - unbonded) to be used as pharmaceutical bottle wadding.

The purpose of this letter is to set forth certain considerations that prompt us to believe this material is suitable for such use.

Whenever Fiberglas products are first introduced into a new application, it is not unusual for the prospective customer to raise questions about both the handling characteristics of the material and possible effects of exposure to it. For example, when several pillow manufacturers, shortly after World War II, were considering the use of Aercor as pillow filling retainer, the question was raised as to whether particles of Fiberglas might work their way through the ticking and, if so, whether there was a possibility that they might cause dermatitis or mechanical injury to the skin. For example, too, when pieces of bonded Aercor were being considered for use as moisture retention pads to replace peat moss in transcontinental shipments of fresh field-cut asparagus, the question was raised as to whether particles of Fiberglas might adhere to the produce and possibly contaminate it. Similar questions have been raised, also about the use of bulk Fiberglas fibers (Basic Fiber No. 26) as pharmaceutical wadding and

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in the packaging of iodine-releasing sterilizing tablets (Wallace & Tiernan [illegible] this application), and for packaging penicillin tablets for oral administration (Grayson Pharmaceutical Co. pioneered this application). In each such instance we have supplied information that has resolved any doubts concerning the propriety of using the specified material for such purposes.

To acquaint you with the subject, it may be helpful to point out, first of all, that Fiberglas products are manufactured in a wide variety of types and fiber sizes. The glass fibers of which they are composed range from broomstraw-thick to gossamer-fine.

Just as nylon is processed into fibers used in whiskbrooms or into hosiery yarns, so glass is manufactured by the Fiberglas processes into relatively coarse fibers of the type used in air filtration, into insulating wool of the type used in ranges and refrigerators and buildings, into continuous filament yarns used to insulate wire and cable or to weave into sheer marquisettes, into down-like Aerocor batts used for clothing interliner, pillow-filling, aircraft seat filling, flexible duct insulation, aircraft and automotive thermal and acoustical insulation, and pads used in crating [illegible] asparagus.

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Although all glass fibers retain some of the basic physical and chemical properties of glass in solid form — they are inorganic, noncombustible, non-toxic, resistant to heat, corrosion, moisture — they derive a new set of physical properties from their fiber form. They become flexible. Glass insulating wool, for example, is resilient, compressible. Glass yarns are woven into fabrics that can be creased and folded. Mats are formed of staple fibers bonded into wafer-thin, porous sheets. Fiberglas Aerocor batts composed of the finest glass fibers manufactured, are extremely light in weight, extremely flexible and resilient, have high thermal and acoustical insulating efficiency.

The physical characteristics of glass fibers vary, too, within the size range of fiber diameters manufactured. Average diameter of the relatively coarse fibers used in air filtration packs, for example, [illegible] times that of the average diameter of the fibers in Aerocor batts (.00005") used in aircraft blankets. Filter fibers have sufficient structural strength to cause traumatic damage to the skin when handled unguardedly; the almost invisible fibers in Aerocor batts have insufficient mass in relation to their diameter to retain any structural strength. The contrast is comparable to that which exists between soft tissue paper and coarse pine shavings.

Within this range of fiber-diameter sizes, there is a point at which the fibers have sufficient structural strength to resist flexing. That the fibers in Fiberglas Aerocor batts are well below this point is demonstrated in a letter[1] from Dr. Karl D. Figley (dated April 4, 1946) describing tests made on Fiberglas Superfine material [now renamed "Aerocor"] to determine whether it was suitable for pillow filling. Dr. Figley writes:

> "In discussing the possibility of any allergenic property of Fiberglas, you will recall that we considered the following:
>
> "Would particles of Fiberglas, through constant use in a pillow work their way through the ticking and give rise to a dermatitis of the face and neck — especially if perspiration were present on the skin? To test this possibility, sometime ago your company furnished me with a quantity of Fiberglas—superfine—labeled XA-PF (S) [now renamed "Aerocor"]. This material was in a very fine powdered form, and was said to be the same material which in batt or roll form is supplied by the Owens-Corning

1/ Photostat attached. Dr. Figley is past president of the American Academy of Allergy.

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Fiberglas Corporation to the L. Buchman Company, Inc., Brooklyn, New York, for filling pillows manufactured by them.

"Upon receipt of this material, it was distributed among the five women employed in my office, Dr. Rawling, and myself -- a total of seven persons. Upon returning each night for a period of ten days, each of these persons rubbed some of this finely-powdered Fiberglas on the moistened skin of the face and neck. Each person reported that there was no dermatitis caused by this procedure after ten nightly applications.

"Therefore, it appears that the possibility is very remote that any contact dermatitis of the face and neck could be caused by sleeping on Fiberglas-stuffed pillows."

Except that it is unbonded with a thermo-setting resin, the material which you are considering for pharmaceutical wadding is similar to the product described by Dr. Figley and to the material now being widely used for pads in shipping field-cut asparagus.

Dr. Figley's letter was included as an exhibit in presentations made to the Council on Physical Medicine of the American Medical Association, on the basis of which the Council listed Fiberglas-filled pillows, fabricated by two manufacturers, as non-allergenic and acceptable for the relief of persons who are allergic to organic pillow fillings. 2/ Further reference to the acceptability of Fiberglas Aercor

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2/ "Fiberglas-Filled Bed Pillows Acceptable", in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, Vol. 132, No. 5 (October 12, 1946), p. 331. (This report covers Fiberglas-filled pillows manufactured by The L. Buchman Co., Inc., Brooklyn, New York.)

"Glasdown Pillows Acceptable", in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, Vol. 134, No. 2 (May 10, 1947), p. 145. (This report covers Fiberglas-filled pillows manufactured by the Glasdown Corporation, Wilkes-Barre, Pennsylvania.)

from a medical point of view is included in Dr. Figley's article 3/ on "House Dust Allergy" in HYGEIA:

> "Glass fibers are now being made that are as soft to down and as resilient as cotton. They are completely nonallergenic. Being composed entirely of inorganic material, and being insoluble in watery fluids, fiber glass /Fiberglas/ is not capable of developing an allergen. It will not harbor molds, nor will it provide nourishment for moths and other insects."

Except that it is unbonded with a thermo-setting resin, the Fiberglas Aerocor (Type M-300) which you are now considering for use as pharmaceutical bottle wadding is similar, also, to the material being supplied by Owens-Corning Fiberglas Corporation to several clothing manufacturers for use as clothing interliner. In an article in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 4/, Dr. Jerome Glaser reported that, because the material is nonallergenic, it may prove invaluable in the case of children unable to tolerate wool in outdoor apparel.

In evaluating the physical characteristics of Fiberglas materials, therefore, it is essential to differentiate the various types of materials under consideration. The point of inflexibility may appear under certain use conditions, when fiber diameter exceeds .00035", but even in the handling of Fiberglas insulating wool of the type used in refrigerators, ranges and water heaters, (where fiber diameter averages .00035") proper hygienic precautions have generally eliminated handling

3/ Karl D. Figley, M. D., "House Dust Allergy", in HYGEIA, Vol. 24, No. 6 (June, 1946), pp. 418-419, 450. Reprint attached.

4/ Glaser, Jerome, M. D. Treatment of eczema (atopic dermatitis) in infancy. JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, 137:6 (June 5) 1948, pp. 527-531. See attached reprint of Fiberglas advertisement, from JAMA (Oct. 23, 1948), captioned "Fiberglas Clothing Interliner Suggested to Relieve Eczema."

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difficulties and reactions are described 5/ as "transitory and superficial."

Of interest in this connection are numerous medical uses of Fiberglas materials 6/ [illegible] purposes as surgical dressings, laparotomy packs, radio-opaque tracer threads in surgical sponges, blood plasma filters, bandages to measure nitrogen loss in the exudate from burned skin, experimental surgical sutures, knitted bandages for fracture casts, and root canal fillings in human teeth, as well as clinical investigations, and wide empirical evidence gained in manufacturing operations involving millions of man-hours' exposure over a period of 15 years which demonstrate that glass in fiber form is a nontoxic, nonallergenic, nonsensitizing, and chemically stable substance that produces no harmful effect upon human tissue.

The fact that Fiberglas Aerocor has no odor or taste and does not impart odor or taste, is attested by the "butter test". Owens-Corning Fiberglas Corporation supplies both Aerocor and another product to insulate domestic refrigerators where odor or other possibility of food contamination is critically appraised. For years a standard quality control test for such Fiberglas refrigerator insulation has been conducted by bringing into an enclosed, high-humidity vessel a slab of unsalted butter and a piece of Fiberglas insulation. After several hours the butter is tested for off-taste. During more than twelve years that Owens-Corning Fiberglas Corporation has supplied this Fiberglas insulation to all the major refrigerator manufacturers, this butter test has been a standard method of testing.

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Undoubtedly it will be reassuring to you to know that — even on the outside chance

5/ Sulzberger, [illegible], M. D., and Baer, Rudolf, M. D., with the technical assistance of Lowenberg, Clare, M. S., and Menzel, Hildegarde, B. S., "The Effects of Fiberglas on Animal and Human Skin—Experimental Investigation" in INDUSTRIAL MEDICINE, Vol. II, No. 10 (October, 1942), pp. 482-484.

6/ Such uses are described and documented with reference to medical literature in the attached brochure entitled "Pioneering Uses of Fiberglas Materials in Medicine."

that some fiber particles might adhere to the tablets and be ingested — such particles would have no deleterious effect. Our files contain several items that may well allay any fears in that score.

In a communication dated May 5, 1936 addressed to our predecessor company, Owens-Illinois Glass Company, Dr. Leroy U. Gardner, director of the Saranac Laboratories, Saranac, New York reported his findings based on a series of ingestion experiments with animals as follows:

To determine whether the ingestion of glass wool particles is capable of injuring the stomach and intestines guinea pigs were fed 2.5 cc. of a 20 per cent suspension of glass particles mixed with their grain 6 days a week, over a period from 4 to 17 weeks, with proper precautions that all of the material was consumed.

Another group received two doses totaling from 0.575 to 0.8 gm. of glass particles, in water suspension, by stomach tube before the morning feedings. When the animals were killed, 4 to 17 weeks later, no trace of the glass or injury produced by it could be discovered in any part of the alimentary tract. Therefore it is concluded that the ingestion of even excessive quantities of glass wool particles 100 microns or less in diameter, produced no injury.

In this same communication the ingestion experiments were described by Dr. Gardner in detail as follows:

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These tests were performed with plain glass wool only as previous tests had indicated that the oiled material did not act differently.

Four fasting guinea pigs were injected by stomach tube with from 1.5 to 6 cc. of a 5% suspension of glass wool ground in a mortar so that the particles were 100 microns and less in diameter. Some

showed any ill effects so the injections were repeated after 23 days. This time doses of 2 to 5 cc. of a 10% suspension were employed and again there were no symptoms. The total doses for the 4 animals were as follows:

#3.....1.5 cc (575 mgm) #3.....4 cc (700 mgm)
#1.....2.0 cc (500 mgm) #2.....6 cc (800 mgm)

Since there was no apparent reaction to these injections, it was decided to continue the administration of the glass, using a 20% suspension mixed with a small portion of grain fed to the animals before they were given their regular morning ration. These 4 guinea pigs and 6 other ones were therefore fed 0.5 gm. of glass 6 days a week until they were killed. The following table summarizes their treatment:

Animal No.	Glass by Stomach tube 1st feeding	2nd feeding	Glass with Food	Total Dose	Duration of Feeding
2	0.3 gm.	0.5 gm.	12.0 gm.	13.8 gm.	32 days
3	0.2 gm.	0.5 gm.	26.5 gm.	27.2	33 days
1	0.1 gm.	0.5 gm.	26.5 gm.	27.1	63 days
4	0.075 gm.	0.5 gm.	39.5 gm.	40.75	94 days
5			13.0 gm.	13.0	30 days
7			26.5 gm.	26.5	61 days
6			39.5 gm.	39.5	92 days
8			51.0	51.0	119 days
9			51.0	51.0	119 days
10			51.0	51.0	119 days

As these animals were killed their intestinal tracts were washed and carefully examined for gross evidence of inflammation. None were found in the mouth, esophagus, stomach, small or large intestines. Representative areas of each portion of the tract and of mesenteric lymph nodes were removed for microscopic section. Examination failed to disclose evidence of the glass fragments or any injury inflicted by them.

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One may therefore conclude that the ingestion of as much as 51 grams of finely powdered glass wool administered in divided doses, will not cause injury in 4 months time. In the absence of any reaction at all it would hardly seem essential to continue the investigation further.

The ingestion experiments carried out by Dr. Gardner at Saranac, as described above, were part of a seven-year program conducted by Dr. Gardner. In addition to the ingestion experiments he carried out injection and inhalation investigations. A detailed report on the other experiments is available in our files, but in the interest of brevity, I include only the foregoing excerpts about the ingestion phase of his experiments, believing that these specifically pertain to your interest.

Attached is a "Transcript of Remarks on Health Aspects of Fiberglas Materials" by W. G. Hazard, P. A. Industrial Hygiene Engineer, U. S. P. H. S. This is an excerpt from the Proceedings of the Rhode Island Industrial Health Institute held in Providence on May 19, 1943.

The following excerpt from this Transcript may be of special interest:

> People have a horror of being injured by glass. It seems deep rooted. When we cut ourselves with a penknife, we think only of the bleeding wound, but when we run afoul of a broken window pane, we think first of the injury and then of the fact that glass caused it. In the last war some of you may recall that enemy spies were said to be sabotaging the home front by mixing peanut butter with ground glass. So serious was this that some able experimenters in Richmond fed animals, and then themselves, ground glass diets to see what would happen. Nothing happened, except in the case of the dogs where there was a slight reddening

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of the [illegible] event. The man lived — and the speaker heard [illegible] their interesting story years later. No authenticated case of poisoning from eating glass among circus performers, [illegible], or anyone else — was found at that time.

The most and most recent evidence that there is nothing [illegible] to poisonous about glass to human tissue comes from surgeons who are today using glass fiber sutures. One of their advantages as given by Dr. Scholz and Dr. Mountjoy is that the glass threads are inert and nonreacting.

* * *

In summary, Fiberglas Aerocor (#-300 - unbonded) of the type which you are now considering for use as pharmaceutical bottle wadding is composed of fibers approximately .000011". Medical authorities approve use of similar material as nonallergenic pillow filling and clothing interliner, and similar material is being widely used in shipping asparagus in direct contact with the produce. Because the material is soft and resilient, being composed of extremely flexible superfine fibers, the individual fibers lack the ability to break off or penetrate material with which they are in physical contact. Even in the unlikely situation that fiber particles might become lodged on the tablets and ingested, Gardner's work demonstrates that the possibility is exceedingly remote that they would have any harmful effect. The fibers are inherently non-toxic, nonsensitizing, nonallergenic.

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Should you wish additional copies of any of the exhibits included with this letter, we would be glad to supply them to you. We hope the data supplied will be helpful to you.

Sincerely yours,

Edward C. Ames/et