dentures in the future. For these rea-
sons, dentures repaired with this kit
should be used only in an emergency
until a dentist can be seen. Dentures
that don’t fit properly cause irritation
and injury to the gums and faster bone
loss, which is permanent. Dentures
that don’t fit properly cause gum
changes that may require surgery for
correction. Continuing irritation and
injury may lead to cancer in the
mouth. You must see your dentist as
soon as possible.

(2) For denture reliners, pads, and
cushions: Use of these preparations or
devices may temporarily decrease the
discomfort; however, their use will not
make the denture fit properly. Special
training and tools are needed to repair
a denture to fit properly. Dentures that
do not fit properly cause irritation
and injury to the gums and faster bone
loss, which is permanent and may re-
quire a completely new denture.
Changes in the gums caused by den-
tures that do not fit properly cause
irritation and injury to the gums and faster bone
loss, which is permanent and may re-
quire surgery for correction. Con-
tinuing irritation and injury may lead
to cancer in the mouth. You must see
your dentist as soon as possible.

(3) If the denture relining or repair-
ing material forms a permanent bond
with the denture, a warning statement
to the following effect should be in-
cluded: “This reliner becomes fixed to
the denture and a completely new den-
ture may be required because of its
use.”

(d) Labeling claims exaggerating the
usefulness or the safety of the material
or failing to disclose all facts relevant
to the claims of usefulness will be re-
garded as false and misleading under
sections 201(n) and 502(a) of the Federal

(e) Regulatory action may be initi-
ated with respect to any article found
within the jurisdiction of the act con-
trary to the provisions of this policy
statement after 90 days following the
date of publication of this section in the
FEDERAL REGISTER.

§ 801.410 Use of impact-resistant
lenses in eyeglasses and sunglasses.

(a) Examination of data available on
the frequency of eye injuries resulting
from the shattering of ordinary crown
glass lenses indicates that the use of
such lenses constitutes an avoidable
hazard to the eye of the wearer.

(b) The consensus of the ophthal-
mic community is that the number of eye
injuries would be substantially reduced
by the use in eyeglasses and sunglasses
of impact-resistant lenses.

(c)(1) To protect the public more ade-
quately from potential eye injury, eye-
glasses and sunglasses must be fitted
with impact-resistant lenses, except in
those cases where the physician or op-
tometrist finds that such lenses will
not fulfill the visual requirements of
the particular patient, directs in writ-
ing the use of other lenses, and gives
written notification thereof to the pa-
tient.

(2) The physician or optometrist
shall have the option of ordering glass
lenses, plastic lenses, or laminated

glass lenses made impact resistant by
any method; however, all such lenses
shall be capable of withstanding the
impact test described in paragraph
(d)(2) of this section.

(3) Each finished impact-resistant
glass lens for prescription use shall be
individually tested for impact resist-
ance and shall be capable of with-
standing the impact test described in
paragraph (d)(2) of this section. Raised
multifocal lenses shall be impact re-
sistant but need not be tested beyond
initial design testing. Prism segment
multifocal, slab-off prism, lenticular
cataract, isetkonic, depressed segment
one-piece multifocal, bioconcave,
myodisc and minus lenticular, custom
laminate and cemented assembly
lenses shall be impact resistant but
need not be subjected to impact test-
ing. To demonstrate that all other
types of impact-resistant lenses, in-
cluding impact-resistant laminated
glass lenses (i.e., lenses other than
those described in the three preceding
sentences of this paragraph (c)(3)), are

capable of withstanding the impact
test described in this regulation, the
manufacturer of these lenses shall sub-
ject to an impact test a statistically
significant sampling of lenses from
each production batch, and the lenses
so tested shall be representative of the
finished forms as worn by the wearer,
including finished forms that are of
minimal lens thickness and have been
subjected to any treatment used to impart impact resistance. All non-prescription lenses and plastic prescription lenses tested on the basis of statistical significance shall be tested in uncut-finished or finished form.

(d)(1) For the purpose of this regulation, the impact test described in paragraph (d)(2) of this section shall be the “referee test,” defined as “one which will be utilized to determine compliance with a regulation.” The referee test provides the Food and Drug Administration with the means of examining a medical device for performance and does not inhibit the manufacturer from using equal or superior test methods. A lens manufacturer shall conduct tests of lenses using the impact test described in paragraph (d)(2) of this section or any equal or superior test. Whatever test is used, the lenses shall be capable of withstanding the impact test described in paragraph (d)(2) of this section if the Food and Drug Administration examines them for performance.

(2) In the impact test, a 5⁄8-inch steel ball weighing approximately 0.56 ounce is dropped from a height of 50 inches upon the horizontal upper surface of the lens. The ball shall strike within a 5⁄8-inch diameter circle located at the geometric center of the lens. The ball may be guided but not restricted in its fall by being dropped through a tube extending to within approximately 4 inches of the lens. To pass the test, the lens must not fracture; for the purpose of this section, a lens will be considered to have fractured if it cracks through its entire thickness, including a laminar layer, if any, and across a complete diameter into two or more pieces, or if any lens material visible to the naked eyes becomes detached from the ocular surface. The test shall be conducted with the lens supported by a tube (1-inch inside diameter, 1 1⁄4-inch outside diameter, and approximately 1-inch high) affixed to a rigid iron or steel base plate. The total weight of the base plate and its rigidly attached fixtures shall be not less than 27 pounds. For lenses of small minimum diameter, a support tube having an outside diameter of less than 1 1⁄4 inches may be used. The support tube shall be made of rigid acrylic plastic, steel, or other suitable substance and shall have securely bonded on the top edge a 3⁄8- by 3⁄8-inch neoprene gasket having a hardness of 40 ± 5, as determined by ASTM Method D 1415–88, “Standard Test Method for Rubber Property—International Hardness” a minimum tensile strength of 1,200 pounds, as determined by ASTM Method D 412–98A, “Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension,” and a minimum ultimate elongation of 400 percent, as determined by ASTM Method D 412–98 (Both methods are incorporated by reference and are available from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428, or available for inspection at the Center for Devices and Radiological Health’s Library, 9200 Corporate Blvd., Rockville, MD 20850, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. The diameter or contour of the lens support may be modified as necessary so that the 3⁄8- by 3⁄8-inch neoprene gasket supports the lens at its periphery.

(e) Copies of invoice(s), shipping document(s), and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, shall be kept and maintained for a period of 3 years; however, the names and addresses of individuals purchasing nonprescription eyeglasses and sunglasses at the retail level need not be kept and maintained by the retailer. The records kept in compliance with this paragraph shall be made available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration or by any other officer or employee acting on behalf of the Secretary of Health and Human Services and such officer or employee shall be permitted to inspect and copy such records, to make such inventories of stock as he deems necessary, and otherwise to check the correctness of such inventories.
(f) In addition, those persons conducting tests in accordance with paragraph (d) of this section shall maintain the results thereof and a description of the test method and of the test apparatus for a period of 3 years. These records shall be made available upon request at any reasonable hour by any officer or employee acting on behalf of the Secretary of Health and Human Services. The persons conducting tests shall permit the officer or employee to inspect and copy the records, to make such inventories of stock as the officer or employee deems necessary, and otherwise to check the correctness of the inventories.

(g) For the purpose of this section, the term “manufacturer” includes an importer for resale. Such importer may have the tests required by paragraph (d) of this section conducted in the country of origin but must make the results thereof available, upon request, to the Food and Drug Administration, as soon as practicable.

(h) All lenses must be impact-resistant except when the physician or optometrist finds that impact-resistant lenses will not fulfill the visual requirements for a particular patient.

(i) This statement of policy does not apply to contact lenses.

§ 801.415 Maximum acceptable level of ozone.

(a) Ozone is a toxic gas with no known useful medical application in specific, adjunctive, or preventive therapy. In order for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals.

(b) Although undesirable physiological effects on the central nervous system, heart, and vision have been reported, the predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema. The onset of pulmonary edema is usually delayed for some hours after exposure; thus, symptomatic response is not a reliable warning of exposure to toxic concentrations of ozone. Since olfactory fatigue develops readily, the odor of ozone is not a reliable index of atmospheric ozone concentration.

(c) A number of devices currently on the market generate ozone by design or as a byproduct. Since exposure to ozone above a certain concentration can be injurious to health, any such device will be considered adulterated and/or misbranded within the meaning of sections 501 and 502 of the act if it is used or intended for use under the following conditions:

(1) In such a manner that it generates ozone at a level in excess of 0.05 part per million by volume of air circulating through the device or causes an accumulation of ozone in excess of 0.05 part per million by volume of air (when measured under standard conditions at 25 °C (77 °F) and 760 millimeters of mercury) in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices. This applies to any such device, whether portable or permanent or part of any system, which generates ozone by design or as an inadvertent or incidental product.

(2) To generate ozone and release it into the atmosphere in hospitals or other establishments occupied by the ill or infirm.

(3) To generate ozone and release it into the atmosphere and does not indicate in its labeling the maximum acceptable concentration of ozone which may be generated (not to exceed 0.05 part per million by volume of air circulating through the device) as established herein and the smallest area in which such device can be used so as not to produce an ozone accumulation in excess of 0.05 part per million.

(4) In any medical condition for which there is no proof of safety and effectiveness.

(5) To generate ozone at a level less than 0.05 part per million by volume of air circulating through the device and it is labeled for use as a germicide or deodorizer.

(d) This section does not affect the present threshold limit value of 0.10 part per million (0.2 milligram per cubic meter) of ozone exposure for an 8-