United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE : January 13, 2004

TO : HS

Through: Todd A. Stevenson, Secretary

FROM : Martha Kosh

SUBJECT: Petition to Declare Natural Rubber Latex a Strong Sensitizer Under the Federal Hazardous Substance Act

ATTACHED ARE COMMENTS ON THE CH 03-4

COMMENT	DATE	SIGNED BY	AFFILIATION
CH03-4-1	11/17/03	Jack Trautman CEO	Allergen Reduction, Inc. 3017 Dianne Dr. Middleton, WE 53562
CH03-4-2	11/20/03	Katrina Cornish Ph.D, FAAAS	US Department of Agriculture Western Regional Research Center 800 Buchanan Street Albany, CA 94710
CH03-4-3	11/26/03	John Friar II	537 Montgomery St. Fall River, MA 02720
CH03-4-4	12/01/03	Carol Kuczora	P.O. Box 536 Grass Valley, CA 95945
CH03-4-5	12/03/03	P. Rourke-Nichols	P.O. Box 2242 Arnold, CA 95223
CH03-4-6	12/04/03	Debra Adkins (Speaker)	Latex Allergy Information Service 176 Roosevelt Ave Torrington, CT 06790
CH03-4-7	12/10/03	Dr. Esah S. Yip	Malaysian Rubber Export Promotion Council 3516 Intern'l Ct, NW Washington, DC 20008

Petition to Declare Natural Rubber Latex a Strong Sensitizer Under the Federal Hazardous Substance Act

CH03-4-8	12/18/03	Margaret Brewster	mrsbrewster@earthlink.net
CH03-4-9	12/18/03	Rhonda Weber	RWeber@irgresources.com
CH03-4-10	12/30/03	Mara Ellingson	rodelling@charter.net
CH03-4-11	01/10/04	William Stone	kstone@sbcglobal.net
CH03-4-12	01/06/04	Judy Hoffman	1311 SE 41 Street, Unit A Cape Coral, FL 33904
CH03-4-13	01/08/04	Rachel Subler Manager of Government Relations and Communications	American Apparel & Footwear Association 1601 N. Kent St, Suite 1200 Arlington, VA 22209
CH03-4-14	12/21/03 **Rec'd 1/8/04**	Noreen Worsnet	376 Bayview Dr. Avon Lake, OH 44012
CH03-4-15	01/08/04	Karen Jakpor Md, MPH	6649 Oakmeadow Dr. Riverside, Ca 92506
CH03-4-16	01/09/04	Linda Shaw	107 Silverwood Lane Cary, NC 27511
CH03-4-17	01/09/04	Laura St George	9237 W Parkview Terrace Loop Eagle River, AK 99577
CH03-4-18	01/09/04 **Rec'd 1/29/04**	Barbara Blakeney President	American Nurses Assoc. 600 Maryland Ave, SW Suite 100 West Washington, DC 20024

ALLERGEN REDUCTION, INC.

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Later comment

November 17, 2003

Rockelle Hammond
Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207

Subject: Comments on Petition HP 00-2 instead of Oral Presentation

We believe that the petition to label natural rubber latex to be unnecessary and if granted would cause serious economic damage to the manufacturers of products containing natural rubber latex. Let me explain our position.

I have been granted U.S. Patent 5,777,004 and have approved PCT's in Japan, Canada and the EU. Using this technology, we have reduced the amount of Type 1 allergens in latex products to one part per million as analyzed by a third party testing laboratory using the best allergen assay available (ELISA). Our recent work indicates that we can reduce the allergen content to 0.1 ppm which is below the present detection level.

Our technology is very economical. The reagents cost is about 0.25 cents per liter of centrifuged latex. For latex exam gloves this equates to about 0.005 cents per pair.

If the Commission does require this label, it would have the effect of elimination any initiative by the manufacturers to reduce the type 1 allergens in their products. We are working with and have Confidential Agreements with several manufacturers of latex containing products. We believe that it is only a matter of time before the consuming public will have the opportunity to select latex products having undetectable allergens. Hence we are asking the Commission to reject Petition HP 00-2.

Thank you,

Jack C Trautman

Jack C. Trautman, Ph.D.
CEO, Allergen Reduction, Inc.

CC:Suzanne Barone

JT:st

Latex

USDA

United States Department of Agriculture

Research, Education and Economics
Agricultural Research Service

November 20, 2003

Mr. Todd Stevenson
Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East West Highway
Bethesda, MD 20814

re: Latex Petition (HP 00-2)

Dear Mr. Stevenson:

I would like to convey some comments and concerns to you regarding the upcoming public meeting announced in the Federal Register for December 10, 2003.

I am the project leader of the US Department of Agriculture's effort to provide domestic natural rubber crops while circumventing Type I (and Type IV) latex allergies. I am especially concerned with ensuring clarity in the development of new declarations, rules and labels. The term "natural rubber latex (NRL)" would be very broadly applicable to latex obtained from at least 2500 different plant species. We have proved that the issues with Type I latex allergy are specific to latex from the Brazilian (or *para*) rubber tree (*Hevea brasiliensis* Muell, Arg.). Latex from different plant species is not the same product, in the same way that beans or nuts from one plant species are not the same as those from other species. Thus, any labeling or declaration regarding the sensitizing power of NRL, if enacted, needs to be specific *only* to Hevea NRL.

To briefly summarize my position, our first domestic rubber crop, guayule (pronounced "why-YOO-lee"), provides all the unique performance advantages of natural rubber but contains only about 2% of the protein in Hevea latex and none of it cross reacts with human Type I Latex Allergy. Guayule latex and latex products have much less protein than was in the properly leached Hevea products that were used safely for many years by high-using sub-groups (e.g. operating room nurses). Also, animal studies indicate no abnormally super-allergenic proteins (such as the castor albumen). The U.S. company commercializing guayule latex, Yulex Corporation of San Diego, will be introducing high quality, low protein, hypoallergenic latex medical products in the immediate future, cured with a procedure that also avoids the use of the allergenic thuriam and carbamate accelerators that induce Type IV contact allergic reactions.

ars
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Agricultural Research - Investing in Your Future

Natural rubber is a strategic raw material, the best performing elastomer available today, and is used in enormous quantities to produce 40,000 different products, and is irreplaceable in high performance applications. It is also a renewable resource and will still be with us when the synthetics made from petroleum are gone. High quality latex from guayule, and potentially from other plant sources, can be used safely by patients suffering from Type I latex allergies because the proteins are different from the proteins in Hevea latex and they do not trigger reactions in sensitized people. Maintaining low protein levels in guayule latex products should ensure that allergies to the new latex materials are not induced in their turn. Unlike Hevea latex products, high protein guayule products would be discolored making processing failures readily detectable. Thus, grouping other natural rubber latices with Hevea natural rubber latex puts us at risk of throwing the baby out with the bathwater.

This is not to say that labeling is inappropriate or unnecessary. In my opinion, labels need to address (i) the issue of sensitization itself, *i.e.* the development of an allergy *and* (ii) address the product's potential to cause a reaction in a person who has already developed the allergy. The threshold protein levels are not the same. The potential of a product to sensitize a person is directly related to the amount of readily soluble protein in the product. Thus, a label of, for example, "soluble protein content of less than 50 $\mu g/dm^2$", could be used to regulate the protein levels in all natural rubber products. However, the presence of any Hevea latex proteins at all could threaten a patient who has already developed Type I latex allergy - for these unfortunates, much lower protein levels than those required to sensitize a person could still induce a potentially life-threatening reaction. Labels to protect these people must reflect the origin of the latex, such as "contains Hevea latex proteins" or "is Hevea latex protein-free".

Type I latex allergy arose when new, inexperienced manufacturers entered the marketplace to meet the demand for latex gloves in response to the Universal Precautions instituted to curb the spread of the AIDS epidemic. These manufacturers eliminated the glove washing step that had been the industry standard - after all the gloves looked and performed similarly whether washed or not. Existing manufacturers followed suit to match the cheaper prices. However, the modified process left large amounts of soluble proteins in the gloves which could then be leached out by the mucosal or bodily fluids of patients. The problem was compounded by the widespread employment of single-use powdered examination gloves in medical settings. Here the proteins migrated, in the box, to coat the powder granules. When gloves were removed before hand perspiration had damped down the powder, the granules were released into the air providing a constant source of exposure to the lung mucosal membranes of all in the building. Recent studies have shown that the use of non-powdered gloves prevents airborne latex allergens allowing many sensitive workers to reenter the workplace.

In conclusion, latex products with low levels of extractable proteins, including Hevea latex products do not seem to be very sensitizing. It is only those latex products with high levels of extractable proteins that are highly sensitizing. I strongly support the elimination of unwashed latex products containing high levels of extractable proteins, especially those that come into direct contact with the mucosal membranes or bodily fluids of people - sites where they can be extracted and induce a response by the human immune system. Unleached dental dams come immediately to mind, in this context. Also, only Hevea natural rubber latex products pose a threat to patients with Type I latex allergies.

Yours sincerely,

Katrina Cornish

Katrina Cornish, Ph.D., FAAAS

JOHN FRIAR II
537 Montgomery Street
Fall River, MA 02720
(508) 672-8955

November 26, 2003
U.S. Consumer Product Safety Commission
Room 502, 4330 East West Highway
Bethesda, MD 20814

Re. Petition to declare Natural Rubber Latex a Strong Sensitizer under the Federal Hazardous Substance Act.

Dear Commissioner:

A finding that natural rubber latex is a strong sensitizer under the Federal Hazardous Substance Control Act would be a giant leap that could only be described as a perversion of the definition of the term "strong sensitizer" under the FHSA regulations.

I am aware of the issues raised, particularly regarding sensitization of health care workers exposed over typically long periods of time, and efforts by producers of latex-based gloves to mitigate those effects. However, my chosen field is elastic thread from natural rubber latex. I have been an employee of four rubber thread companies as both an engineer and chemist, one of which was, until recently, owned by me. I have also been a consultant to many other producers of natural rubber latex fibers. Almost everyone in the United States wears our product every day in his or her underwear without incident.

In manufacturing, of rubber thread I have seen employees experience allergic reaction to the Kraft paper used in the cardboard boxes of the finished product packaging; and allergic reactions to some of the chemicals used in their compounds, such as dithiocarbamates and mercaptobenzothiazoles. I have also seen dry skin arising from excessive exposure to the talc used for dusting the thread. But I have never, since my entry into the business 35 years ago, seen an allergic reaction by a worker to the latex itself, or the dried vulcanizate made therefrom. I realize that "never" is a strong word, but it is my observation.

That is not to say that I have not been told of problems: About twelve years ago I received a call from a customer about a spina bifida patient (a ten year old child) who experienced anaphylaxis when he slept with a "Koosh Ball" against his cheek. It was made from our rubber thread. He salivated extensively and had an anaphykactic reaction, requiring emergency room treatment. But I would argue that this does not rise to the requirement that it is a substance "which will cause on normal living tissue... a hypersensitivity". Rather, I argue that the effects seen to date are by and large on tissue that has been made a bit abnormal by exposure under extraordinary circumstances that now largely no longer exist.

For these reasons I believe the petition should be DENIED.

Thank you for the opportunity to comment on this important issue.

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Later Comm 4

P.O. Box 536
Grass Valley, CA 95945

December 1, 2003

Suzanne Barone, Ph.D.
Project Manager for Poison Prevention
Division of Health Sciences
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Dear Ms Barone,

Re: Petition for a rule declaring natural rubber latex a strong sensitizer

When people are sensitized to rubber, the experience is bewildering because there are lots of things they don't know. I summarize some of those things here for their benefit. For instance, they don't know:

- that rubber is a hydrocarbon
- that most rubber is synthetic, not natural
- that there are lots of recipes for rubber
- that stability of rubber and other polymers varies with age
- that new and old polymers give off gases and particles that enter the lungs
- that both natural and synthetic rubber contain many toxic additives
- that there are many types of hypersensitivities, not just those we think of as "allergies"
- that many substances can cause them, not just plants and animals
- that antibodies to those substances cross-react with others we can no longer avoid
- that hypersensitivity reactions vary over time due to immunoglobulins' delay and half-lives
- that symptoms can affect any or all parts of the body, not just skin and noses
- that some of those symptoms can be life-threatening.

I didn't know.

But you know.

Clearly, there is a problem with finished rubber products. CPSC staff summaries and responses to comments illustrated that you are well aware of the relevant chemistry, toxicology, immunology, and epidemiology. Yet, you disregarded the facts and comments. You know better than the petitioner what is needed. The petition was too restrictive. Your responses were even more restrictive, and you added impossible hurdles. Then, you recommended denial of the petition on the basis of standards of proof that cannot be met.

Semantics

The petition in question, oddly enough, limits attention to "natural rubber latex." That is a term for the raw milk from the rubber tree. The choice of terms seems inappropriate because when referring to finished products, "rubber" should be the noun; "natural" and "latex" should be the adjectives. Worse, the terms "natural" and "latex" are both so ambiguous as to be misleading and almost useless. For instance:

- "Natural latex" is the colloidal liquid exuded by the rubber tree, containing 95% cis-isoprene.
- The term "natural latex" has also been applied to synthetic cis-isoprene, manufactured from petroleum by means of a stereospecific enzyme that arranges the methyl (CH3) groups.
- Most synthetic rubber is trans-isoprene, with methyl groups on either side of the carbon chain.
- Gutta percha is also of a natural vegetable source, but it is trans-isoprene and not called "natural."
- "Latex," in general, is a term applied to any substance with similar spreading properties, such as so-called "latex" paint, which is polyacrylate or polyacetate, derived from petroleum.
- What is called "natural rubber latex" contains lots of synthetic additives -- known strong sensitizers.

What's new?

If natural latex were responsible for the epidemic of hypersensitivity to rubber, harvesters would get sensitized, and we would have had this epidemic for the last 150 years, not just 15 years. What changed? Lots of things: More additives; more synthetics; more speed that leaves unreacted monomer or intermediate chemicals or unkilled catalists; and more ozone, which triggers autoxidation, the escalating splitting of molecules into reactive epoxide gases. You cannot blame the rubber tree. That would not be honest.

Another thing changed: Panels of tests of hypersensitivity to rubber and chemicals used to be cited in medical textbooks (Fisher, 1973; Cronin, 1980). After hypersensitivities became epidemic in the '80s, the tests became unavailable, at least in this country, so that no patients could document their illness or injury. This blocked workers compensation and toxic torts, but also made it impossible to do epidemiology and prevention.

Rubber additives

Reported symptoms are very likely due to rubber additives, which are known to include lots of toxicants and sensitizers. This list is not comprehensive:

- **Reinforcing and filling materials** -- asbestos powder, talc, limestone, silicon dioxide
- **Colors** -- phthalocyanine, iron oxide, titanium dioxide
- **Plasticizers, softeners** -- oils, oxidized petroleum residues, tars, coal tar distillates
- **Curing or vulcanizing agents** -- sulfur, benzoyl peroxide, nitrogenous aromatic compounds, diisocyanates, dinitroso compounds
- **Accelerators** -- thiurams, dithiocarbamates, zinc alkylxanthates, nitrosomethylaniline, diphenylguanidine, mercaptobenzothiazole
- **Antioxidants** -- naphthylamines, phenylenediamine, quinolines, diphenols
- **Fragrances** -- synthetics derived from petroleum and coal, commonly sensitizers
- **Synthetic copolymers** -- acrylonitrile (vinyl cyanide)

Synthetic rubber

Since 1962, world consumption of synthetic rubber has surpassed that of natural rubber. In the U.S., production of synthetic rubber, especially SBR, far surpassed that of other countries. All rubber molecules consist of repeating links in a carbon chain (polymers of monomers). Many of the links are airborne carcinogens and powerful sensitizers individually. There are many recipes for "rubber":

- Styrene-butadiene copolymer -- (SBR, GR-S, Buna-S)
- Nitrile (Buna-N) -- A copolymer of butadiene and acrylonitrile
- Butyl -- A copolymer of isobutylene and small amounts of isoprene or other hydrocarbon
- Neoprene -- A polymer of chloroprene
- Thiokols -- Compounds of an ethylene dihalide and an alkali polysulfide
- Stereospecific rubbers -- cis-polyisoprene and cis-polybutadiene

My exposure experience

I was sensitized to rapidly oxidizing old foam rubber, then cross-reacted to other alkenes and terpenes and polar aromatics. Suddenly my life changed because I couldn't breathe around vinyl flooring, new carpet, tar, dye, diesel exhaust, hair products, fabric softener, dry cleaning, fragrances -- the list goes on.

Since no doctor would admit to knowing anything about such sensitivities, I studied. Those substances have in common that they vaporize to enter the blood through the lungs, and that they form epoxides, which bind to one's proteins and nucleic acids, making the chemicals carcinogens as well as sensitizers.

I thought I was the first to get poisoned on rubber, and could prevent an epidemic. But doctors denied it could happen, though the epidemic had already started. They refused to test for hypersensitivity to rubber or for delayed hypersensitivity. An IgE test was negative for Type I hypersensitivity to plant and animal proteins, of course, to which I do not react anyway.

My systemic and cardiac symptoms pointed to Type II (cytotoxic) and Type III (immune complex) hypersensitivities, mediated by IgG and IgM antibodies, which are large proteins. Pulmonary symptoms could be Type IV (cell-mediated, delayed), since skin contact allergens can cause havoc in the lungs. I also learned that foam rubber (my initial sensitizer) is frothed with soaps and gelling agents such as sodium silicofluoride (Encyclopedia Britannica 1969), which is a rat poison (Merck Index 1983).

I suffered insults, shunning, and discounting, by doctors, employer, coworkers, and family. I was referred to charlatans, by association with whom patients are routinely discredited. That turned out to be typical.

Barriers to prevention

The CPSC is responding to the petition and complaints by limiting its attention only to those things that cannot be documented and by insisting that everything must be known about proteins and prevalance before anything can be done. That's not possible. That's not necessary.

Most of us can't get counted, so prevalence cannot be established. There is a pattern of doctors' laughing off hypersensitivities to toxic chemicals, including rubber, and referring the afflicted to psychiatrists and alternative practitioners. This after a propaganda campaign that included workshops funded by Sandoz for allergists and doctors of occupational medicine at medical conferences in the early '90s.

While the petition was restricted to the least likely causative substance, your responses were restricted to the least likely causative mechanism. You disregarded all physiological mechanisms of symptoms of toxicity other than one immune response mediated by one immunoglobulin, IgE.

One commenter (CH00453) requested that the toxic components be removed. The CPSC responded that they were trying to identify all the proteins. That disregarded and sidestepped the comment. Another commenter (CH00456) complained about reaction to carpet adhesive, to which you responded that it was "not accessible." However, you know it gives off fumes of volatile organic compounds (VOC's), or poison gas.

You made labeling or other regulation contingent upon what cannot be counted, quantified, characterized, documented, or proved. You recommended denial of the petition on that basis of that impossibility. Thereby, CPSC set up a catch 22 for affected patients that makes documentation impossible, and ties its own hands, perpetuating the epidemic. Surely, the chemical companies appreciate your efforts.

It isn't necessary to quantify the number of people affected, to what degree, the amount of allergen that sensitizes or that evokes a reaction in the previously sensitized. It isn't necessary to characterize every trace protein in rubber or to prove which of them may be causative agents. All that needs to be known is known: Finished rubber products contain toxicants, and chronic illness and deaths are proliferating.

Requests of CPSC

We should be talking about rubber, and the CPSC should be addressing any and all rubber components likely to be responsible for symptoms, and any and all physiological mechanisms, including all types of hypersensitivities mediated by all types of immune cells and antibodies, not just IgE.

- The words "natural" and "latex" should be deleted from the petition.
- Rubber manufacturing processes must be regulated and monitored.
- *In vivo* skin tests of hypersensitivity to different rubbers and additives, without regard to whether irritant or immune or by which immunoglobulin, must be made available in this country again. If tests of IgE reactivity to natural latex rubber is negative, test for IgG, IgM, and cell-mediated hypersensitivity to several types of rubber and to common rubber additives.
- Research should be aimed at the most likely sources of the problems -- toxicants -- not the least likely -- proteins.
- If the trace amounts of proteins in natural latex are found to be a problem, rinse them out. They are water-soluble; you don't need to characterize any of them.
- If double carbon bonds in addition polymers are the problem, use ammonia to donate protons to saturate them so they don't form epoxides or bind human macromolecules.
- If toxic additives are the problem, leave them out.
- Count us. Solicit cases as the CPSC did in the Toxic Carpet campaign of 1989.

When in doubt, do it all. Manufacturers used to know how to make rubber safer, and can be required to do so again. I demand a good-faith effort to remove all sensitizers and toxicants and carcinogens from rubber and other synthetic polymers.

Sincerely,

Carol Kuczora

Carol Kuczora

December 3, 2003

To The Consumer Product Safety Commission,

I wish I could be present to speak to you in person. What I have to tell you is better done face to face. But, I have a Type I Immediate Hypersensitivity to Natural Rubber Latex Proteins, and I am not allowed to fly. Many airports have switched, from the natural rubber latex gloves they started using so urgently after 9-11,to safer synthetic gloves and that is a great step. But, my doctor feels that air travel isn't very safe for me since it would be almost impossible to provide emergency treatment for me if I had an unexpected exposure to natural rubber latex proteins in the air and had an allergic reaction while in flight.

I cannot address the issue of natural rubber latex proteins being a "strong sensitizer" as I am not a scientist. What I can address is the need to label packaging as to natural rubber latex content as I am a consumer of many products who has a severe allergy to natural rubber latex proteins.

On shopping day I must make a detailed list of what we need, that isn't out of the ordinary. When we get to the store I must don my 3M particulate respirator and look at my watch as we enter the store. On a "good day" I have about 40 minutes of shopping time, with my mask on. On a bad day I just don't shop. My husband and I divide the list and away we go to complete our tasks in the allotted time. This usually works well for us.

Now, in the holiday frenzy, I must avoid the stores all together as there are too many triggers in there for my latex allergy induced asthma to tolerate, even with a mask on. When we buy our items we have to read all labels to make sure an item is safe to bring in to our home. My home living requirements are for a "latex free environment". Even after 5 years we are still trying to achieve that. We must scrutinize every item before it is allowed in the house. If an item is clearly marked as "latex free" then it can come in. If an item is not labeled and it may contain natural rubber latex I can't take a chance. I can write down the consumer phone number, go home and call. The first reply is never enough and more research must usually be done to identify any natural rubber latex content. This can take days, weeks and sometimes they never find the correct information. This is very time consuming and I usually end up without the item I needed in the first place.

I have included 4 items for you to view and compare the labels on them. I want to point out how easy it is for the manufacturer to add this to the labels of their products. It makes shopping quicker and safer for me and thousands of others who have this life, health and career-altering allergy.

The first items are cosmetic sponges that are made by the same company. The back of the first package is clearly labeled "non-latex'. I know, with a glance, that this is an item I may purchase and safely bring in to my home. The second package of cosmetic sponges, in the Ziploc bag, does not mention latex content at all so they are not safe for me to handle (my husband did the packaging, the Ziploc bags are a latex safe product) or to use. I am preventing a possible allergic reaction by not using the unlabeled product. I am keeping myself latex free by using the product that is labeled the same.

The second items are baby bottle nipples. Infants are also at risk for natural rubber latex allergy and if the parent has the allergy a properly labeled baby item can save a life and precious time. The first package of clear nipples is clearly labeled as silicone. The second set of nipples, in the Ziploc bag, is clearly labeled as "Latex nipples". This alerts consumers with latex allergy that these nipples are made of latex and they know it is something they should not buy.

The third items are *Band-Aids* and *Comfort Strips*. I included these to show how confusing the issue can be. Both boxes have a strong caution on them "The packaging of this product contains natural rubber latex which may cause allergic reactions." The irony here is that the bandage itself if latex free but the package that it is wrapped in is not latex free. My husband has to open and toss all bandage packing for me.

The fourth items are dishwashing gloves. The first package is clearly labeled "LATEX- FREE". I know I can buy and use these gloves safely without worry of an allergic reaction. The second package of gloves, in the Ziploc bag, have gone the extra measure and added a caution, not just a label, "This product contains natural rubber latex which may cause allergic reactions in some individuals....". Kudos to the company for looking out for consumers with latex allergy and having the caution on the package.

I think these examples clearly show the reason we are requesting that consumer products be labeled as to their natural rubber latex content. As a consumer with this allergy I need to know if a product is safe for me to buy and use. My family and friends need to know if an item they wish to purchase for me is latex safe or not. If it isn't on the package then who will know?

I want to thank you for your time and attention to this matter. As I said before, I am not a scientist or specialist in this field; but I am educating myself on all aspects of this allergy so I may live safely. I don't have any degrees or science to share with you but what I do have to share is what life if like with a Type I Allergy to Natural Rubber Latex Proteins. It is full of daily challenges to maintain the balance of latex free living and shopping as a consumer with special needs. If you have any questions or need more information please do not hesitate to contact me.

In all things important—be well.

Sincerely Yours,

Peggy Rourke-Nichols, R.N.

Peggy Rourke-Nichols, former R.N. of 23 years
now disabled due to type I allergy to
natural rubber latex proteins
PO Box 2242
Arnold, California 95223
209-795-4943

enclosed :
4 NIOSH
2 packages of cosmetic sponges
2 packages of baby nipples
2 boxes of bandages
2 pair of dishwashing gloves
3 copies of this letter

DEBRA M. ADKINS

December 4, 2003

Office of the Secretary,
Consumer Product Safety Commission,
Room 502, 4330 East-West Highway,
Bethesda, Maryland 20814.

Dear Rockelle Hammond:

As the petitioner and former editor of Latex Allergy News I'd like to acknowledge the Commission's consideration of my petition and thank the Commissioners for holding a public hearing I wish I could attend, but health considerations make it impossible. If possible, I would appreciate it if a staff member, such as Suzanne Barone, would read this statement at the hearing, and show the enclosed video. I will take this opportunity to write comments on the Executive Summary for the staff's recommendation to deny the petition.

First, I note that Summary paragraphs five and six refer to "medical personnel" as a population with "high exposure to NRL-containing gloves". This contrasts with the briefing package data reporting that the prevalence of NRL allergy in healthcare workers ranges from 2.2 to 17 percent". The perceived and actual difference between "medical personnel" and "healthcare workers" is critical to the Commission's final decision since it "must consider the frequency of occurrence". "Medical personnel" is only one subcategory of the Census Bureau's NAICS Class 62/"Healthcare and Social Assistance", that totaled 6,237,768 in 2002, or 6.84% of all adults over 18 years of age. While 6.84% alone is very significant, it looms even larger when you factor the "societal value" of healthcare workers, Healthcare and Social Assistance shortages, combined with this new age of terrorism.

The Summary's description of "people who have multiple surgeries" also fails to convey an essential criterion for your ruling; the "severity of the reaction", considering the 29 to 65 percent of latex allergy sufferers among those disabled by Spina Bifida. In this regard, the Summary notes that; "The petition also requests specifically that toys and other articles intended for use by children, which contain NRL, be labeled".

Another questionable Summary statement is; "Exposure of the general population to NRL is unknown". This is effectively contradicted by TAB C/Page 2's statement that: "the most frequently cited estimate of the number of types NRL or DNR products is 40,000, including industrial, medical and consumer products"; and that, "virtually all consumers are regularly exposed to some NRL or DNR

products unless they make special efforts to avoid it". It's hard to imagine anyone always avoiding, no less knowing, all of TAB B Appendix's partial list of "Household Products that may be manufactured from NRL or DNR".(And people without a latex allergy frequently buy products for someone with latex allergy - known or unbeknownst.) On the issue of labeling, I find your comments and response an insult to the Consumer! "Labeling would alarm and confuse the consumers who are otherwise unaffected by NRL, and discourage them from using beneficial product." If a consumer has a sensitivity or allergy to peanuts, regulated by the FDA, they can read the label, and avoid exposure to that item. If a consumer has a latex allergy or sensitivity, there is no labeling, and no way to know if the product contains an allergy to NRL, because the CPSC does not see a need for labels. The consumer expects there to be a warning on everything that they buy. I have mistakenly purchased toys for my grandchildren; nieces and nephews had no warnings, and caused problems in for me,

. From the moment of birth, through out our lives and even after death we are exposed to NRL. Every thing from diapers to toys, Basketballs to tennis balls, shoes, sneakers, balloons, adhesives, mattresses, rain boots, swim caps, weather stripping, driveway sealant, and many questionable such as floor covering and carpet backing, the glue in envelopes, gaskets. There is such an array of products that may or may not contain NRL, I suggest the manufactures use "This product does not contain any Natural Rubber Latex" and see how many consumers stay away from those products.

A final troubling Summary statement is that; "There are very few NRL-containing products for which there are documented allergic reactions". Perhaps it depends upon what the meaning of "documented" is. The briefing package "References" contains several cases, even a squash ball! (Warshaw, E.M.(1998). "Latex Allergy." J Am Acad Dermatol 39(1):1-24.) I am sure those attending this hearing can describe similar personal allergic encounters with NRL-containing products, despite their "hyperawareness " of the dangers. "As one of tens of thousands of healthcare workers "latex-retired" by severe reactions to NRL-consumer products that compounded minor and subsequent severe reactions to medical devices, I urge the Commission to approve my petition for NRL (if not for DNR) to help millions of others avoid a similar loss of livelihood and life threatening allergic reactions."

Re Children:

It should be noted that latex balloons are the only one of the three dipped over the counter (OTC) products that isn't at least partially covered by FDA labeling. Even most retail, non-medical gloves now have latex labeling. Unfortunately, this exception exposes children to the high protein solid and aerated allergen levels of the dipped latex product with the least quality controls; especially the preponderant imports. The enclosed video shows what latex aeroallergen looks like from a one-minute segment on the syndicated TV Show, EXTRA.

Some statements from the FDA's Final Rule on labeling NRL-containing medical devices, published in the September 30, 1997 Federal Register, are relevant to the Commission's consideration:

The FDA" summary concludes: "These requirements are being established in response to numerous reports of severe allergic reactions and deaths related to a wide range of medical devices containing natural rubber".

Regarding NRL-containing condoms, FDA's Background states:' The agency (disagrees and) will require latex condoms to bear a labeling statement that the product contains natural rubber latex that may cause allergic reactions. Although consumers may be aware that the product contains latex, FDA believes that the additional information that natural rubber may cause allergic reactions is essential information to individuals who are not aware that natural rubber latex may cause allergic reactions."

I would add, that it's understandable why latex allergy sufferers and their parents, ask why, aside from the luck of the "Agency draw", condoms must be latex-labeled, while others, including vulnerable children, must risk potentially life threatening exposure to latex-laden balloons and "covered-up" latex products such as underwear. From my own experience, the covered products do not shield one from life-threatening allergic attacks.

Finally, FDA's Background states: "An individual who is sensitive to natural latex proteins is equally likely to react to an OTC device that contains natural rubber. Therefore, it is equally important to provide essential information about OTC devises that contain NRL as it is to provide information about prescription devises that contain natural rubber Latex

Sincerely,

Debra m. Adkins

across a range of depths to test the efficiency of the gear across a range of scup-Loligo densities. Samples would be within close proximity of one another to minimize steam time between stations. Estimated catch for the study period are as follows: Loligo squid, 96,000 lb (43,545 kg); scup, 13,000 lb (6,078 kg); butterfish, 9,600 lb (4,354 kg); Illex squid, 2,800 lb (1,270 kg); summer flounder, 2,600 lb (1,179 kg); monkfish, 1,900 lb (862 kg); smooth dogfish, 1,000 lb (454 kg); spiny dogfish, 700 lb (318 kg); white hake, 600 lb (272 kg); john dory, 200 lb (91 kg); black sea bass, 100 lb (45 kg); silver hake, 100 lb (45 kg); and tilefish, 10 lb (5 kg). Squid and fish caught during the study would be sold by the vessel owners, in accordance with the requirements of the permits issued to them (with the exception of the requested exemption to the scup landing limit). The sale of fish is necessary to offset the costs of chartering the vessels for the study. The participating vessels would be required to comply with applicable state landing laws and report all landings on the Federal Fishing Vessel Trip Report.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 7, 2003.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 03–28547 Filed 11–13–03; 8:45 am]

BILLING CODE 3510-22-S

CONSUMER PRODUCT SAFETY COMMISSION

Public Meeting Concerning Petition for Rule Declaring Natural Rubber Latex a Strong Sensitizer

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of public meeting.

SUMMARY: The Consumer Product Safety Commission ("CPSC" or "Commission") will conduct a public meeting on December 10, 2003, to receive comments concerning Petition HP 00–2, which requested that the Commission declare natural rubber latex ("NRL") to be a strong sensitizer under the Federal Hazardous Substances Act ("FHSA"). The CPSC staff's briefing package recommends that the Commission deny the petition. The Commission invites oral presentations from members of the public with information or comments related to the petition or the staff's briefing package. The Commission will consider these presentations as it decides what action to take on the petition.

DATES: The meeting will begin at 10 a.m. on December 10, 2003. Requests to make oral presentations, and 10 copies of the text of the presentation, must be received by the CPSC Office of the Secretary no later than December 3, 2003. Persons making presentations at the meeting should provide an additional 25 copies for dissemination on the date of the meeting.

The Commission reserves the right to limit the number of persons who make presentations and the duration of their presentations. To prevent duplicative presentations, groups will be directed to designate a spokesperson.

Written submissions, in addition to, or instead of, an oral presentation may be sent to the address listed below and will be accepted until January 10, 2003.

ADDRESSES: The meeting will be in room 420 of the Bethesda Towers Building, 4330 East-West Highway, Bethesda, MD. Requests to make oral presentations, and texts of oral presentations should be captioned "Latex Petition Briefing" and be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, or delivered to that office, room 502, 4330 East-West Highway, Bethesda, Maryland 20814. Requests and texts of oral presentations may also be submitted by facsimile to (301) 504–0127 or by e-mail to *cpsc-os@cpsc.gov.*

FOR FURTHER INFORMATION CONTACT: For information about the purpose or subject matter of this meeting contact Suzanne Barone, Ph.D., Directorate for Health Sciences, U.S. Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–7256; e-mail: *sbarone@cpsc.gov.* For information about the schedule for submission of requests to make oral presentations and submission of texts of oral presentations, contact Rockelle Hammond, Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–6833; fax (301) 504–0127; e-mail *rhammond@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The Commission received a petition from Debi Adkins, editor of Latex Allergy News, requesting that the Commission issue a rule declaring natural rubber latex ("NRL") to be a strong sensitizer under the Federal Hazardous Substances Act ("FHSA") and that consumer products containing NRL be labeled. The petitioner asserts that a portion of the population has developed an allergy to NRL that can cause serious allergic reactions, even death. NRL may be in such consumer products as gloves, adhesives, shoes, balloons, pacifiers, and carpet backing, as well as many medical products.

The Commission published a notice in the **Federal Register** on March 21, 2000, requesting comments on the petition. 65 FR 15133. The Commission extended the comment period 30 days. 65 FR 33525. The Commission received a total of 85 comments on the petition.

The staff reviewed the petition, comments and other relevant available information. The staff then forwarded a briefing package to the Commission, which is available on the Commission's Web site *www.cpsc.gov* or from the Commission's Office of the Secretary. The staff recommends that the Commission deny the petition. The staff concludes that available data do not support that NRL is a strong sensitizer as that term is defined in the FHSA. Current scientific information about the development of NRL allergy from consumer products that contain NRL is limited, and it does not appear that the information will be developed in the near future.

The FHSA defines the term "strong sensitizer" as a "substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance" and which the Commission declares to be a strong sensitizer. 15 U.S.C. 1261(k). The FHSA definition further states that before making such a declaration, and "upon consideration of the frequency of occurrence and severity of the reaction, [the Commission] shall find that the substance has a significant potential for causing hypersensitivity." *Id.*

B. The Public Meeting

The purpose of the public meeting is to provide a forum for oral presentations on the NRL petition and the CPSC staff briefing package.

Participation in the meeting is open. See the **DATES** section of this notice for information on making requests to give oral presentations at the meeting and on making written submissions.

Dated: November 7, 2003.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 03–28458 Filed 11–13–03; 8:45 am]

BILLING CODE 6355-01-P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

"significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the rules docket. A copy of it may be obtained by contacting the rules docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 USC 106(g) 40113, 44701.

§39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

97-20-11 Socata—Groupe Aerospatiale: Amendment 39-10148; Docket No. 97-CE-15-AD.

Applicability: Model TBM 700 airplanes (serial numbers 1 through 109), certificated in any category, that do not have the main landing gear (MLG) inboard doors and the door locking control mechanism removed (MOD 70-065-32) in accordance with the Technical Instruction of Modification OPT70 KO59-32, dated December 1995, as referenced in Socata Service Bulletin (SB) 70-073, dated June 1996.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required within the next 100 hours time-in-service after the effective date of this AD or within the next 6 calendar months after the effective date of this AD, whichever occurs first, unless already accomplished.

To prevent the MLG from failing to extend because of corroded MLG inboard locking hinges, which could result in loss of control of the airplane during landing operations, accomplish the following:

(a) Remove the MLG inboard doors and the door locking control mechanism (MOD 70-065-32) in accordance with the Technical Instruction of Modification OPT70 KO59-32, dated December 1995, as referenced in Socata SB 70-073, Amdt. 1, dated June 1996.

(b) As of the effective date of this AD, no person may undo MOD 70-065-32 on any affected airplane, by reinstalling the MLG inboard doors and the door locking control mechanism.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(e) The removal required by this AD shall be done in accordance with the Technical Instruction of Modification OPT70 KO59-32, dated December 1995, as referenced in Socata Service Bulletin 70-073, Amdt. 1, dated June 1996. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Socata—Groupe Aerospatiale, Socata Product Support, Aeroport Tarbes-Ossun-Lourdes, B P 930, 65009 Tarbes Cedex, France; or the Product Support Manager Socata—Groupe Aerospatiale, North Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri; or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(f) This amendment (39-10148) becomes effective on November 13, 1997.

Issued in Kansas City, Missouri, on September 24, 1997.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97-25832 Filed 9-29-97; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0119]

21 CFR Part 801

Natural Rubber-Containing Medical Devices; User Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule requiring labeling statements on medical devices, including device packaging containing natural rubber that contacts humans. The rule requires labeling of medical devices containing natural rubber latex that contacts humans to state: "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."; labeling of medical devices containing dry natural rubber that contacts humans to state: "This Product Contains Dry Natural Rubber."; labeling of medical devices containing natural rubber latex in their packaging that contacts humans to state: "Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."; labeling of medical devices containing dry natural rubber in their packaging that contacts humans to state: "The Packaging of This Product Contains Dry Natural Rubber."; and that the claim of hypoallergenicity be removed from the labeling of medical devices that contain natural rubber. These requirements are being established in response to numerous reports of severe allergic reactions and deaths related to a wide range of medical devices containing natural rubber.

EFFECTIVE DATE: This final rule is effective September 30, 1998.

FOR FURTHER INFORMATION CONTACT: Donald E. Marlowe, Center for Devices and Radiological Health (HFZ-100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850, 301-443-2444, FAX 301-443-2296.

SUPPLEMENTARY INFORMATION:

I. Background

Natural latex is a milky fluid obtained in commercial quantities primarily from the *Heavea brasiliensis* (rubber) tree. There is often confusion concerning the terminology used to describe the raw agricultural materials derived from rubber-producing plants; products made from various intermediate forms of the

in a device is intended to contact or is likely to contact the user or patient (e.g., latex medical gloves or latex enema tips). This includes contact when the device that contains natural rubber is connected to the patient by a liquid path or an enclosed gas path (e.g., intervenous administration sets, or blood collection or transfusion tubing with natural rubber injection ports, injection syringes with natural rubbe plungers, or natural rubber tubing or connector components used in anesthesia or endoscopic insufflator circuits). This also includes contact when the device that contains natura rubber is fully or partially coated wit a powder, and such powder may can natural rubber proteins that may contaminate the environment of the or patient (e.g., latex tourniquets). Tl definition makes it clear that the labeling statement is required on devices that have an intended use th could reasonably be expected to introduce natural latex proteins to humans.

5. Several comments suggested tha the natural rubber labeling statement be expanded to apply to nonmedical natural rubber latex gloves and other consumer products that contain natural rubber. Other comments suggested that medical devices sold over-the-counter (OTC) to the consumer be exempt from the labeling requirements in order to avoid confusion regarding the natural rubber-content of other consumer goods that would not be subject to this labeling regulation.

The agency disagrees that the regulation should apply to nonmedic natural rubber latex gloves and other consumer products that contain natu rubber. The regulation of such produ is beyond the scope of this rule. FDA authority under the act to impose labeling requirements is restricted to products that meet the definition of foods, drugs, cosmetics, animal drug biologics, and devices, as those term are defined under the act. This rule applies to devices as defined under section 201(h) of the act (21 U.S.C. 321(h)). Under section 201(h) of the act, a device is:

* * * an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is * * * intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals * * *, and which does not achieve any of its principle intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Latex gloves and other products are subject to this rule, only if they meet the definition of device under section 201(h) of the act. Latex gloves that are not used in the cure, mitigation, treatment or prevention of disease are not devices within the meaning of section 201(h) of the act, and, therefore, are not subject to this rule. Latex medical gloves that are subject to this regulation include surgeon's gloves, as classified at 21 CFR 878.4460, and patient examination gloves, as classified at 21 CFR 880.6250.

FDA also does not agree with the suggestion that OTC medical devices be exempted from the labeling requirements in order to avoid confusion with natural rubber products that are not subject to this rule. The purpose of the labeling requirement is to provide essential information for individuals sensitive to natural latex proteins. An individual who is sensitive to natural latex proteins is equally likely to react to an OTC device that contains natural rubber, as to a prescription device that contains natural rubber. Therefore, it is equally important to provide essential information about OTC devices that contain natural rubber, as it is to provide information about prescription devices that contain natural rubber. Moreover, the agency does not believe that labeling, as required by this rule, on OTC devices, will cause significant confusion regarding the natural rubber content of consumer products that are not devices.

6. Several comments requested clarification on the applicability of the requirements to certain devices. Specifically, the comments asked whether the rule would apply to: Bandages with natural rubber in the adhesive; natural rubber-free devices packaged in a wrapper using natural rubber in the adhesive, especially where the adhesive would contact human tissue while unwrapping the device; foods or natural rubber-free devices handled or applied with natural rubber latex gloves; covered elastic stretch bands used to attach an accessory or component to a device; or, devices intended to contact only subcutaneous tissue.

A labeling statement is required for devices that contain natural rubber when the natural rubber contacts humans, as described in § 801.437(b) of the final rule. Accordingly, devices intended to contact subcutaneous tissue would be required to bear the appropriate statement.

Moreover, bandages with natural rubber in the adhesive would require the labeling statement. For this product, the natural rubber is intended to be applied directly to the skin. If natural rubber-containing adhesives in tapes, bindings, and similar items are intended to contact, or are likely to contact, the user or the patient, they are required to be labeled under this regulation. Covered elastic bands would not be considered to be in contact with humans, provided the covering blocks the migration of natural rubber proteins to the patient and user.

FDA does not believe it would be appropriate to require natural rubber labeling statements for natural rubber-free devices or foods that may be handled with latex gloves. As described previously in comment 5 of this document, requiring natural rubber labeling for products, such as foods, that are not devices is beyond the scope of this regulation. Moreover, FDA does not believe that requiring products that are handled by latex gloves, regardless of whether such products coul the scope of this regulation is appropriate if such pro contain natural rubber. Req labeling on products that no not come into contact with ... gloves would confuse consumers and would be impracticable to implement. Furthermore, FDA is not aware of any reports of allergic reactions to rubber free products that latex gloves have contacted.

Under the final rule, natural rubber containing packaging adhesives that typically are in areas that hold the flaps of packaging together would meet the criteria to subject the product to this rule only if they contact the patient or user. However, the agency is not aware of any evidence or reports of reactions to packaging adhesives. Given the pervasiveness of the use of adhesives that contain some amount of natural rubber latex, the lack of evidence that these adhesives cause adverse reactions, and the ability to open packaging with adhesives without coming into contact with the adhesives, the agency concludes that the adhesives in device packaging are not intended to contact humans and are not likely to contact humans. Therefore, if such adhesives are the sole source of natural rubber in the device packaging or the device itself, a device with such packaging would not be subject to this rule.

The agency stresses, however, that it considers device packaging to be an integral part of a device. Under section 201(h) of the act, a device includes components, parts, or accessories. As accessory to a device, the packaging a device under section 201(h)(1). A device that contains natural rubber in

its packaging, beyond that found in the adhesive (e.g., a device packaged in a latex sheath) is likely to contact the user or patient and must be labeled as containing natural rubber.

In order to avoid confusion and to clarify to the consumer whether it is the device itself or its packaging that contains natural rubber, however, the agency believes that a distinct labeling statement is appropriate for devices that have packaging that contains natural rubber that contacts humans. Accordingly, under § 801.437(f) and (g) of the final regulation, such devices shall have labeling with one of the following statements: "Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions." or "The Packag of This Product Contains Dry Natur Rubber."

The agency notes that if one of th packaging statements is required, it shall appear regardless of whether t is a natural rubber statement relatir the product itself. For example, a d that contains dry natural rubber thi contacts humans and is also packa dry natural rubber that contacts hu shall be labeled with both the statements: "Caution: The Packagi g of This Product Contains Dry Natural Rubber." and "This Product Contains Dry Natural Rubber."

7. Several comments suggested that the labeling statements be required only on finished medical devices, and that device components be exempt.

The agency agrees in part. The regulation applies to all finished devices and components that are intended to contact or are likely to contact the user or patient. The labeling statement does not apply to components shipped directly to a manufacturer or processor for use in the manufacture of a device because these components, during t time before distribution to consume would not be intended to contact, c likely to contact the user or patient Under these circumstances, the par components are not accessible to h care workers or patients. If, howev device component is sold directly consumer, including a patient or h care worker, and it is intended to contact or likely to contact a user c patient, it is required to be labeled under this regulation, regardless o whether it must be attached, inser used in conjunction with other de Replacement parts marketed as accessories for medical devices th intended to contact or likely to co a user or patient also require the labeling statement.

8. One comment suggested that in vitro diagnostic devices be exempt because only dry natural rubber is used, there is usually no patient contact with the natural rubber components, and space is very limited for labeling. One comment suggested that other devices that do not contact the patient be exempted, regardless of whether the natural rubber contacts the tissues of the health care worker.

The agency believes that in vitro diagnostic devices should be exempt only to the extent that the natural rubber used in vitro diagnostic devices is not intended to contact or is not likely to contact the user or the patient. FDA, however, is requiring labeling for such devices if they are intended to contact or are likely to contact health care workers or other users, as well as the patient, because all latex-sensitive persons who use the device need to be informed of the product's natural rubber content.

9. One comment requested an exemption for the labeling of natural rubber latex condoms because such condoms clearly contain latex. The comment also believed an exemption should apply to latex condoms because space for labeling is limited, a warning regarding allergic reactions may have a chilling effect on the use by individuals who are not sensitive to natural rubber, and the statement may lead to confusion in differentiating between latex and natural skin condoms because natural skin condoms also contain some natural rubber latex and would require the statement as well.

The agency disagrees and will require latex condoms to bear a labeling statement that the product contains natural rubber latex that may cause allergic reactions. Even though consumers may be aware that the product contains latex, FDA believes that the additional information that natural rubber latex may cause allergic reactions is essential information to individuals who are not aware that natural rubber latex may cause allergic reactions. The agency believes that there is sufficient room on condom packaging for the required statement.

FDA does not believe that the statement will have a chilling effect on the use of condoms by individuals who are not sensitive to natural latex proteins. The statement, however, would clearly provide important information to individuals who are sensitive to natural latex proteins.

The agency further disagrees with the suggestion that the labeling statement would be required on natural skin condoms, and thereby confuse consumers with respect to the differences between latex and natural skin condoms. Although natural skin condoms do contain a natural rubber elastic band, this band is wrapped within the natural skin sheath, and there is no evidence to indicate that the natural rubber ever contacts the user. Therefore, natural skin condoms that have a latex component that is not intended to contact or likely to contact the user do not require the labeling statement. Accordingly, the absence of any latex labeling requirement for natural skin condoms obviates the comments concern about confusion that may result from latex labeling statements on both latex and natural skin condoms.

10. Although most comments supported the requirements of standard labeling requirements, some comments suggested that the proposed labeling statements were overly prescriptive, and that manufacturers should have wide latitude in the wording of the statement provided it contain a general latex ingredient statement. Other comments stated that the labeling statements did not provide sufficient warnings, and suggested that the agency require a caution stating that use of the device may lead to chronic asthma, dermatitis, or even anaphylactic shock and death.

The agency does not agree with comments suggesting the labeling should state possible reactions with specificity. FDA believes that the statement advising consumers that a product may cause an allergic reaction is specific enough to provide adequate warning.

The agency also does not believe that the required labeling statements are overly prescriptive and that manufacturers should be given wide latitude in the wording of labeling statements. The agency has determined that requiring standardized statements for devices containing natural rubber is the best approach for providing the essential information in a clear, consistent, and accurate manner.

FDA realizes that there may be some circumstances where it may be appropriate to tailor specific information concerning a device. If a manufacturer believes use of statements that vary from those prescribed by this regulation is appropriate, § 801.437(i) of the final regulation provides that the manufacturer may petition the agency for an exemption or variance from these requirements by submitting a citizen petition under 21 CFR 10.30. Unless the agency has specifically granted an exemption or variance, the agency will consider any variation from the required statement to be noncompliant, and the device will be deemed misbranded.

11. Several comments suggested that the agency recommend the use of

Malaysian Rubber Export Promotion Council

3516 International Court, N.W., Washington DC 20008 Tel: (202) 572 9771 Fax: (202) 572 9787

Comments by Dr. Esah S. Yip
to the
Consumer Product Safety Commission
Public Hearing on Petition HP 00-2

December 10, 2003

Thank you for the opportunity to speak to you today. My name is Dr. Esah Yip, and I am the U.S. director of the Malaysian Rubber Export Promotion Council. As you may know, Malaysia is the largest exporter of natural rubber latex medical gloves to the United States. As such, we are sensitive to the problem of latex allergy and take this issue very seriously.

I am here today to express support for the Commission staff's recommendation of Oct. 10, 2003, to reject Petition HP 00-2, which seeks to classify natural rubber latex (NRL), as well as products containing NRL, as a "strong sensitizer" under the Federal Hazardous Substances Act (FHSA), and be labeled accordingly. I would also like to congratulate the CPSC staff for producing an excellent and thorough report on the subject. MREPC agrees that natural rubber latex, and products that contain NRL, should not be classified as a strong sensitizer, for the following reasons:

(1) NRL is *NOT* a Consumer Product

First, NRL or natural rubber latex is not in itself a consumer product. It is a raw material used in the manufacture of NRL products. "Latex" is technically defined as a "stable colloidal dispersion of polymeric substance in a liquid medium." Once the raw latex is converted into its solid products, the liquid latex state of the polymeric material no longer exists. Therefore, it is not correct to classify NRL itself as a consumer product that is a strong sensitizer.

(2) NRL Does Not Meet the Definition of a "Strong Sensitizer" in Accordance with the Federal Hazardous Substance Act (FHSA)

According to the FHSA, a strong sensitizer must have significant potential for causing hypersensitivity, and the frequency occurrence and severity of the reaction must also be considered. For a product containing a strong sensitizer to be a hazardous substance and

to require cautionary labeling under the FHSA, the product must be capable of causing substantial personal injury or substantial illness during or as a result of customary or reasonably foreseeable handling or use. To this end, MREPC's view is consistent with the Commission's report that:

- ***NRL Allergy Has Little Impact on the General Public***

  The prevalence of latex protein allergy among the general population has been estimated to be about 1 percent or less by the FDA and others (Liss *et. al.* 1999). The most severe form of NRL allergy, anaphylaxis, has been estimated to affect only 0.00008 percent of the American population annually.

  While there are some 40,000 industrial, medical, and consumer products that are either made of natural rubber or contain the polymer, documented clinical reactions are limited to only a small number of NRL consumer products, such as balloons and particularly gloves.

  The majority of these 40,000 products are dry natural rubber products, which are processed differently from NRL goods such as gloves, condoms and balloons. Dry rubber products have in fact been shown to contain very little residual soluble proteins and allergen activity as indicated by RAST-inhibition assay[1,2] as well as negligible allergenicity when skin tested on latex sensitive individuals[1].

- ***Insufficient Evidence Exists***

  Medical gloves
  Although more than 2,000 cases of adverse reactions allegedly due to latex allergies related to medical gloves have been reported to the FDA since the early 1960's, none of these cases was clinically verified, and the reactions reported could be due to causes other than latex protein. FDA disclaimers clearly state that "*A report of other information submitted by a reporting entity and any release by FDA of the report or information, does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, or the reporting entity or its employees, caused or contributes to the reportable event.*"

  Food service gloves
  The Center for Food Safety and Applied Nutrition (CFSAN) of the FDA has also received about 75 self-reported cases of food-mediated latex allergic reactions related to food handling using NRL gloves. Again, none of these cases has been clinically verified through medical records, and CFSAN, in its report presented at the Food Protection Conference last year in Nashville, pointed out that "it is possible that some of the reactions described could have been due to consumption of foods that cross react with latex protein (e.g., kiwi, buckwheat, stone fruits, potatoes, tomatoes, sweet pepper, chestnuts, spinach, etc.)"

In fact, at a recent meeting the Additives and Ingredients Subcommittee of the Food Advisory Committee concluded that there is insufficient scientific evidence to establish that the use of NRL gloves in food handling could cause allergic reaction through food ingestion.

- *Clean-room, household and industrial gloves*
  Using current technology, these gloves are often chlorinated, a process involving extensive washing during the chlorination treatment, whereby most of the residual soluble proteins are removed.

(3) Recent Manufacturing Advances Reduce Latex Protein

While it is true, as Ms. Atkins alleges, that the greater availability of latex products has brought greater awareness of the potential for allergic reactions, manufacturers are taking steps to address this problem. In Malaysia, where production of NRL medical gloves is a significant industry – which supplies nearly half of the medical gloves used in the United States – considerable time and effort has gone into finding a solution. One of the positive outcomes has been the development of a new generation of low-protein natural rubber latex gloves that are not only very effective in barrier protection, but also vastly reduce the risk of latex protein allergy. To ensure that these low-protein gloves are manufactured to the highest standard, Malaysia has also instituted the Standard Malaysian Glove program (SMG), which requires participating manufacturers to adhere to rigorous testing requirements.

According to a number of studies[3-8], the use of low-protein/allergen gloves not only markedly reduces the incidence of latex protein allergy and allows latex allergic healthcare workers donning non-latex gloves to work alongside their colleagues wearing NRL gloves, but also:

- Dramatically decreases the atmospheric loads of NRL antigens to undetectable levels within 24 hours after glove change;
- Allows latex allergic healthcare workers to continue to carry out their usual work assignments with no symptoms or complications due to the allergy.
- Can allow even latex allergic healthcare workers to use very low-allergen NRL gloves. The study that put forward this finding also showed that only a few workers with previous experience in anaphylactic reactions needed latex-free gloves. No latex allergic healthcare workers had to change tasks within the workplace, or retire because of latex allergy.

(4) Benefits of Natural Rubber Products

Natural rubber is one of the most useful gifts bestowed to man by nature. The unique properties of the natural rubber polymer imparted to its products have benefited mankind in many ways. For example:

- Natural rubber latex gloves have prevented the loss of many lives because of their excellent barrier performance against viral transmission such as HIV and other infections diseases, as well as many other critical glove properties that manufacturers of synthetic gloves are attempting to achieve;

- Because of the very low heat build-up of the natural rubber polymer, it is an essential ingredient for the making of tires for heavy vehicles, particularly aircraft, which encounter a tremendous amount of friction and heat build-up during taking off and landing. The operation could otherwise be dangerous and unsafe.

Furthermore, natural rubber is a "green" material. As it is derived from trees, natural rubber is biodegradable, unlike many synthetic substitutes, which are made mostly from petrochemicals. As, such, their manufacturing and disposal processes could be hazardous to the environment.

(5) Unintended Negative Consequences

If NRL products required cautionary labeling, many consumers would be alarmed or confused and discouraged from using the natural rubber products that provide significant benefits, such as gloves and condoms. This is not withstanding the fact that these people may not be affected by the NRL allergy.

Furthermore, unwarranted cautionary labeling would not only have an economic impact associated with cost of labeling, but also could result in a decrease in the use of NRL products, both of which would have a serious impact on small businesses.

Conclusion

In light of the points discussed above, MREPC urges the Commission to stand by its staff recommendation to deny petition HP 00-2. I would once more like to thank the Commission for the opportunity to share our views with you.

References:

1. *Yip E. and Cacioli P.* The Manufacture of Gloves From Natural Rubber Latex. J. Allergy Clin. Immunol. 2002; 110: S3-14.

2. *Hunt L., Kelkar P., Reeds C.E., Yunginger J. W.* Management of Occupational Allergy to Natural Rubber Latex in a Medical Center: the Importance of Quantitative Latex Allergen Measurement and Objective Follow-up. J. Allergy Clin. Immunol. 2002; 110: S96-106.

3. *Tarlo S.M., Easty A., Dubanks K., Min F., and Liss G.* Outcomes of a Natural Rubber Latex (NRL) Control Program in an Ontario Teaching Hospital. J. allergy Clin. Immunol. 2001; 108: 628-633.

4. *Reuff F., Schopf P., and Prybilla B.* Parameters of Natural Rubber Latex (NRL) Sensitization Decrease in Healthcare Workers (HCW) Following Reduction of NRL Exposure. Presented at 56th annual meeting of the American Academy of Asthma, Allergy and Immunology (AAAAI) in 2000.

5. *Allmers H., Brehler R., Chen Z., Raulf-Heimsoth M. Fels H. and Baur X.* Reduction of Latex Aeroallergens and Latex-Specific IgE Antibodies in Sensitized Workers after Removal of Powdered Natural Rubber Latex Gloves in a Hospital. J. Allergy Clin. Immunol. 1998; 102:841-846.

6. *Turjanmaa K., Kanto M., Kautianien H., Reunala T. and Palosuo T.* Long-term Outcome of 160 Adult Patients with Natural Rubber Latex Allergy. J. Allergy Clin. Immunol. 2002; 110: S70-74.

7. *Allmers H, Schmenfler J. and Skudik C.J.* Primary Prevention of Natural Rubber Latex Allergy in the German health Care System Through Education and Intervention. J. Allergy Clin. Immunol. 2002; 110(2): 318-323.

8. *Kelly K.J., Klancnik M., Kurup V., Barrios-Jankol C., Fink J.N. and Petsonk E.L.* A Four-Year Prospective Study to Evaluate the Efficacy of Glove Interventions in Preventing Natural Latex Sensitization in Healthcare Workers at Two Hospitals. J. Allergy Clin. Immunol. 2003; 111(2), No. 426.

Latex comment 8

Stevenson, Todd A.

From: Dudley Brewster [mrsbrewster@earthlink.net]
Sent: Thursday, December 18, 2003 9:35 AM
To: Stevenson, Todd A.
Subject: Latex Petition

Good Morning, My name is Mrs. Margaret Brewster. I have Latex allergies. The company that I woke for has seem fit to retire me. Products should let people know it is has NRL. I have had experience with going through a allergic reaction to find out that product has NRL. My allergies are severe that I can Die. I recently had surgery and the hospital was very attentive towards me concerning my allergies. But the tape they used on me after call Cabon tape is latex. I had a allergic reaction to it. God's Blessing that It was not life threaten this time. The reason is that I am at home where I am safe and my sensitivity is not has bad has it was. But if I had kept the tape on longer it would have. Because I did have a reaction. Please label products, next time I may not be able to write you.

thank you,

--- Margaret Brewster
--- mrsbrewster@earthlink.net
--- EarthLink: It's your Internet.

Stevenson, Todd A.

From: RWeber@irgresources.com
Sent: Thursday, December 18, 2003 3:35 PM
To: Stevenson, Todd A.
Subject: "latex Petition Briefing"

I am writing in support for the above mentioned bill for labeling consumer products with nrl. I know this would make my potential for any allergic reaction much less as I could make more choices in the foods, products that I purchase.
Thanks in advance for your attention to this urgent concern.

Rhonda Weber, RN
Latex allergy individual

Letter Comment 10

Stevenson, Todd A.

From: Information Center
Sent: Tuesday, December 30, 2003 4:58 PM
To: 'rodelling@charter.net'
Subject: latex petition briefing

Hello,

We have forwarded your request to the appropriate agency personnel.

Please be advised that the Federal Trade Commission (FTC) also has jurisdiction over labeling of products. You can contact the FTC toll-free at 1-877-382-4357 or via their web site at www.ftc.gov.

Please be advised that you may obtain CPSC publications, recalls and general safety related information via our web site at www.cpsc.gov. Click on the "Search" icon and type in your topic. You may also file an incident report via the web site mentioned above. If you have additional inquiries, you may call our toll-free hotline at 1-800-638-2772, Monday - Friday, 8:30am to 5:00pm, Eastern Standard Time. Press 1 to begin and then press 3 to speak with a representative.

tm

-----Original Message-----
From: rod [mailto:rodelling@charter.net]
Sent: Tuesday, December 30, 2003 4:21 PM
To: Information Center
Subject: latex petition briefing

to whom it may concern: i have a severe latex allergy--it keeps me from working, shopping and other normal daily things. there are over 40,000 products in the market now that contain natural rubber latex, it is very difficult to know what is safe to bring into our home and what isn't. PLEASE,PLEASE require labels to be put on products. This is a matter of life or death for me!
sincerely,
mara ellingson

Later BP 11

Stevenson, Todd A.

From: William Kenneth Stone [kstone@sbcglobal.net]
Sent: Sunday, January 04, 2004 7:55 PM
To: Stevenson, Todd A.
Subject: latex petition breifing

In my town of 80,000, five of the people who work at Mercy Hospital have had to be retired on medical disability because of anaphylaxis to natural rubber latex. The hospital has taken the measures of banning powdered latex gloves there in response to this problem but there continue to be problems with contact allergy to latex. Approximately 10% of health care workers have contact allergy to natural rubber latex. I had my second anaphylactic reaction to latex in January of 2000. This caused my retirement. I continue to have to carry an epinephrine pen with me at all times because of the risk of anaphylaxis. This reaction was unfortunate for me as well as my community. I was one of the two board certified vascular surgeons in my community and had to give up all of this after twenty years of caring for patients. The allergy is still present as I can still feel when I am in the atmosphere around latex such as in a tire store and in a store that sells tennis shoes which are bound with latex based glue. I would find it helpful if products were labeled if they contained rubber latex as it is had to find shoes and other products that contain no natural rubber latex. I hope that you can extrapolate the experience in this small town to the rest of the country to see what a large problem this is. I strongly support the labeling of natural rubber latex as a hazardous materiel. W. Kenneth Stone, M.D.

Office of the Secretary
Consumer Product Safety Commission
Washington, D.C. 20207
Fax: 301-504-0127
Email: cpsc-os@cpsc.gov

LATEX PETITION BRIEFING

'My throat is swelling.' 'My chest feels like it is getting tight.' 'The thoracic pain is excruciating.' 'Why am I so short of breath?' Where's my (Benedryl) diphenhydramine? 'My BP's dropping. Where's my epi?

Shortly after taking the diphenhydramine, I experienced additional symptoms: swelling of the throat, flushing, weakness, decreased BP, wheezing, respiratory distress, anaphylaxis. What is going on I thought? The diphenhydramine is supposed to be helping. Why do I feel worse?

K-Mart American Fare reported after I called a couple days later and confirmed upon inquiry–they use latex gloves to handle all of there medications. (2001)

'Boy, my chest sure feels tight.' 'What's going on? All I did was eat some **Pepperidge Farms Gold Crackers**.' A call to Pepperidge Farms confirmed that all their foods are processed with personnel wearing latex gloves. (2001)

Wheeze, wheeze–right sided chest pain (most likely bronchial constriction). 'Can someone get my inhaler? PLEASE' 'My chest is getting tight, I'm getting short of breath?' 'All I have eaten this evening is plain spaghetti with tomato sauce.' 'Are tomatoes cross reactive with latex?'

Latex Allergy Links web page with information on cross reactives confirmed '**tomatoes**' are cross reactive with natural rubber latex.

These are just a few of my experiences within the first 6 months after I was diagnosed with Latex Allergy Type 1 & 4, in October 2000. It's been an ongoing nightmare since then. Shoes, undergarments, the Post Office, every grocery store, the shopping malls, the sports complex, most restaurants, government buildings, real estate offices, (obviously) doctor's offices, emergency medical services, schools and churches. These are just of few of the places and things that have caused me problems due to the use of hevea brasiliensis/natural rubber tree products: to include, but not limited to, latex gloves, latex balloon, and rubberbands (in excessive quantities).

I worked as a Registered Nurse for 16 years in SW Florida and only became aware that latex allergy was an issue for some 'patients,' in 1999. How to provide care to 'patients' afflicted by Latex Allergy was incorporated into our CEU's (continuing education units), 1999/2000. I never received the memo about nurses being at extremely high risk for sensitization–perhaps because the glove manufacturers failed to send one. They knew since the 1980's, but didn't bother to tell the rest of us. We had to find out the hard way. Like Asbestos and Black Lung (Coal Miners), now there's Latex Allergy afflicting 25% of healthcare providers. Well, at least the ones properly diagnosed.

There's a whole generation on the rise to latex sensitization–ALL THE **CHILDREN IN THE DAY CARES** USING LATEX POWDERED GLOVES. They have NO CLUE. Latex gloves are really cheap these days and no one has bothered to warn the folks outside of the healthcare arena, that ***latex sensitization*** is a real and significant issue.

Such as:

Auto mechanics
Hair dressers
Deli & Bakeries
Food services
Housekeepers
Teenagers (confidentially) and young adults using latex prophylactics
Construction workers (to protect from plaster)

At any time, after exposure as children in the day cares using latex gloves/balloons, a child–teenager–young adult, never having had significant symptoms, can go to any one of the aforementioned locations and without any preemptive warnings, experience an anaphylactic reaction from untoward exposure to microscopic aerosolized natural rubber latex proteins floating ***eternally*** in an air conditioned building. Just sitting in the dentist chair, or coming into close personal contact with someone who has been handling gloves or balloons, can result in an anaphylactic reaction, or worse - DEATH. Anyone who is diagnosed with Latex Allergy type 4 is at high risk to develop type 1.

Now imagine the nightmare for those of use who are aware. Knowing that before we go anywhere we have to call, inquire, 'check it out'–or don't go. Before hugging someone, screening them for secondary exposure. Or wondering if our mail was handled by latex gloves or bond with latex rubberbands. And the need to know which foods and medications have been prepared with or exposed to latex gloves.

Persons seriously afflicted by latex allergy (type 1) have been denied benefits (Work Comp, Disability). We have been extensively discounted, many of us having helped so many others throughout our careers. We have been discriminated against, in violation of the ADA[1] of 1990. We have suffered physically, emotionally and financially. Some, God rest their souls, have DIED.

PLEASE HELP US.

Please help facilitate awareness through the CPSC, not only to protect those already afflicted, but perhaps to prevent others from suffering mortality or morbidity.

[1] Americans with Disabilities Act of 1990 – a medical condition that effects one or more major life functions or can result in DEATH. **Latex Allergy Type 1** fits that bill.

There is no doubt, compared to some, I am very fortunate. My ***Multiple Chemical Sensitization/ADA of 1990*** by **Latex Allergy Type 1** has only landed me in the emergency room 1 time. For the most part, as long as I was still breathing, I would refuse to go–fear of death and financial reasons. My medication consumption is limited because there are some many uncertainties of cross reactives and processing exposure, I feel I'm better off doing without–provided I can maintain "strict avoidance of latex."

At 43 years of age, I know my life will fraught with challenge from now until the good Lord calls me home. But, I would sure appreciate it if you could make it just a little easier, a little safer for myself and others in the same position.

Our blessed soldiers have sacrificed their lives for people in a different country to have a better way of life. Can't the CPSC make a difference in the lives of folks here at home that need your help?

Please grant the petition to label products and such containing natural rubber latex. Anything else you can do would be greatly appreciated too. Thank you.

Sincerely,

Judy Winslow Hoffman, Disabled RN–*Multiple Chemical Sensitization*/ADA of 1990
1311 SE 41 Street, Unit A by Latex Allergy Type 1 (since 2000)
Cape Coral, Fl 33904
(239) 549-0211
Email: Latexsafe@aol.com

http://designbymarco.tripod.com/latexallergyeducation

courtesy of Marcos Cardoso: www.capecoralwebdesigner.com

Cc: Office of the Secretary, CPSC, on 1/6/2004
via fax #301-504-0127 and email: cpsc-os@cpsc.gov

Stevenson, Todd A.

From: Latexsafe@aol.com
Sent: Tuesday, January 06, 2004 10:23 PM
To: Stevenson, Todd A.
Subject: LATEX PETITION BRIEFING

Office of the Secretary
Consumer Product Safety Commission
Washington, D.C. 20207
Fax: 301-504-0127
Email: cpsc-os@cpsc.gov

LATEX PETITION BRIEFING

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courtesy of Marcos Cardoso: www.capecoralwebdesigner.com

1/7/2004

Cc: Office of the Secretary, CPSC, on 1/6/2004
via fax #301-504-0127 and email: cpsc-os@cpsc.gov

Additionally, an attachment copy included.

Late Cor 13

8 January 2004

Office of the Secretary
Consumer Product Safety Commission
4330 East-West Highway Room 502
Bethesda, MD 20814

RE: Petition HP 00-2, to declare Natural Rubber Latex a "Strong Sensitizer"

Per the Federal Register notice announcing a public meeting and the opportunity to submit written comments *(68 F.R. 64610, November 14, 2003)* the American Apparel & Footwear Association ("AAFA") is pleased to offer these comments on the petition asking the Consumer Product Safety Commission ("CPSC") to declare natural rubber latex ("NRL") and products containing NRL "strong sensitizers" under the Federal Hazardous Substance Act.

As stated in our comments of 21 June 2000, AAFA, (at that time the organization was known as the American Apparel Manufacturers Association, or "AAMA") believes that there continues to be no objective evidence or data to support a conclusion or proposed rulemaking that wearing apparel products containing NRL should be declared strong sensitizers. AAFA continues to oppose the petition.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Rachel Subler at 703.797.9039 or by email at: rsubler@apparelandfootwear.org.

12/21/07 Ltr. Comm 14

Dear Consumer Product Safety Commission,

I am so sorry that I did not do my part by sending this letter to you sooner. It is my understanding that you denied the petition requesting that products containing natural rubber latex list it as a content. I guess I never thought that such a logical request would ever be denied. Therefore - I am writing to state my disbelief and disappointment. My son was exposed to latex during emergency abdominal surgery at 6 weeks of age to correct a life threatening malrotation of his intestines. This was 16 years ago - years before anyone heard of latex allergy. However he had an extreme allergic reaction to latex at age 4 and we have been trying to weed

out for latex in everyday life since then, it is next to impossible however — a simple product identification would make our lives -- and all those who are candidates for anaphalaxis much easier, safer, bearable.

Please, I would like you to reconsider this request. It is the right thing to do.

Sincerely

Noreen Worsnet

Karen Jakpor, MD, MPH
6649 Oakmeadow Dr.
Riverside, CA 92506

January 8, 2004

Office of the Secretary,
Consumer Product Safety Commission
Washington, DC 20207
Attn.: Suzanne Barone, Ph.D., Directorate for Health Sciences

RE: LATEX PETITION BRIEFING

To Whom It May Concern:

I am writing in support of Petition HP00-2 to classify natural rubber latex (NRL) a strong sensitizer under the Federal Hazardous Substances Act. I also support labeling consumer rubber products that contain NRL.

Furthermore, I request that the CPSC take action that would cause the manufacturers of natural rubber latex gloves used by nonmedical personnel to reduce the allergen content of their gloves and to label their gloves. CPSC should at a minimum apply the same standards that the FDA has used to regulate natural rubber latex gloves used in the medical field and also the proposed rule to place limits on the protein content of gloves. But I believe that there is good reason for CPSC to go further than the FDA and ban the use of powdered latex gloves among non-medical personnel and consumers. There is certainly not any argument in the benefit: risk analysis that would suggest any benefit to consumers using powdered latex gloves as opposed to nonlatex or powderfree latex gloves. But we know there is a risk to using powdered latex gloves. So if there is no benefit, but proven risk, the CPSC should intervene and not just ignore the problem.

Also, please see that in the NIOSH Alert in 1997 they recommend that powdered latex gloves never be used, and powderfree low-allergen latex gloves be used only when deemed absolutely necessary for barrier protection.OSHA has already issued a citation and fine against a nursing home for latex glove use for non-patient tasks. OSHA found that Highland Acres was not in compliance under 29 CFR 1910.138 (b): "The Employer did not base the selection of the appropriate hand protection on an evaluation of the performance characteristics of the hand protection. Employees who performed non-patient care tasks such as kitchen duties and housekeeping were provided with latex exam gloves."

Why would powdered latex gloves be any safer for consumers than medical personnel? Why should consumer gloves be unregulated? In fact, there is reason to suspect that powdered latex gloves currently sold to consumers might be more hazardous because of "glove dumping," just as the pharmaceutical industry has been involved in "drug dumping" to Third World nations. In 1997, at the time when many hospitals started

buying nonlatex and powderfree latex gloves, I noticed that rows upon rows of boxes of the hazardous powdered latex gloves showed up on the shelf of my local club where house store. Several years ago, when I called a motel to inquire about what type of gloves they used for cleaning, the motel personnel said that the hospital had just donated to them a large amount of powdered latex gloves.

Latex glove use is widespread outside of the hospital environment—i.e. food service, daycare, hair styling and beauty services, dental services, security check-points, cleaning services, toll booth collectors etc. The fact that consumers and workers in these fields outside of medicine receive no warning and no education about the risk of latex allergy reveals unequal treatment and is discriminatory. Perhaps CPSC should also embark on a national educational campaign to provide the public with information about the risks of latex allergy and the availability of safer alternative products.

I also request that the CPSC take action that would cause the manufacturers of latex balloons, "Koosh Balls," latex pacifiers and latex bottle nipples to wash the latex more and reduce the allergen content of their products or ban those hazardous products. Ideally, I'd like to see CPSC ban latex balloons for more than one reason—both the risk of latex allergy and the risk of death due to children choking on pieces of latex balloons. CPSC is already aware that more children die from latex balloons than from all the toys that have been recalled because of dangers to children.

I believe latex nipples and pacifiers should be banned, because silicone is a good safe alternative. Infants do not need unecessary early mucosal exposure to latex allergen. Especially children with Spina Bifida or a history of multiple surgeries should not be exposed to these. But at the very least, there should be a warning label so parents can make their own informed decisions.

I understand from a leading allergist that Koosh balls particularly pose a danger because they have a large surface area.

Another consumer item of particular concern is latex resistive exercise bands. These are powdered like latex gloves and they are snapped around. Nonlatex resistive exercise bands such as Repbands are an excellent and safer alternative at about the same cost. The reason I am particularly concerned about consumer powdered NRL gloves, latex balloons, powdered latex condoms, and resistive exercise bands, is that they pose the greatest potential threat to health. These products are made of "dipped" latex and tend to have higher allergen content than products made of hard dry natural rubber. They also pose a danger because they are powdered. Aerosolized latex can harm latex allergic individuals even without direct physical contact, because the powdered latex is breathed into the lungs and may cause severe asthma and systemic reactions.

Hair glue is another dangerous consumer product (even though it is not powdered). I understand a death occurred in England due to exposure to hair glue.

I understand that latex condoms are under the jurisdiction of the FDA.

It is easy to understand that mattresses should be labeled as to whether or not they contain natural rubber latex. Otherwise, it might be difficult for the consumer to tell. Especially since latex mattresses and latex foam pillows are often advertised as "hypoallergenic." I believe the CPSC should make a rule that would prohibit the use of the term "hypoallergenic" with latex foam mattresses and pillows. That term is clearly inappropriate and misleading. The FDA took action prohibiting glove manufacturers from labeling their "brown gloves" as hypoallergenic. CPSC should take similar action.

I am a latex-allergic physician and I am a member of the Consumer Rubber Products subcommittee of ASTM. I did my residency in obstetrics and gynecology at a Harvard hospital and I received my MD and MPH from the University of Michigan. I am not aware of any actions taken by ASTM to reduce the allergen content of latex balloons, "latex Koosh balls," latex nipples and pacifiers, latex mattresses, or latex resistive exercise bands. I've been a member of ASTM since 1997. It seems unlikely that any voluntary standard will be developed by ASTM to improve the safety of these products. Latex balloons contain powder that can become aerosolized and cause the same breathing hazard as powdered latex gloves. The Mayo Clinics did studies that documented very high allergen content of latex balloons. In fact, they found a latex balloon contained 4700 allergen units/ml, a level higher than many of the latex gloves that they tested. (Yunginger JW et al., "Extractable latex allergens and proteins in disposable medical glove and other rubber products," J Allergy Clin Immunol., 1994 May; 93(5):836-42.)

I know first hand the risk of latex balloons. Several exposures to latex balloons have resulted in my being admitted to the hospital or treated in the ER for severe asthma or anaphylaxis. Just for some background, I became severely allergic to latex in 1996 after heavy exposure to latex aeroallergen at work and at home where I was caring for an ill family member. I've had numerous hospitalizations for severe asthma or anaphylaxis as a result of latex exposures—powdered latex gloves or latex balloons. I've seen several of the leading allergists who are experts in latex allergy. The diagnosis of latex allergy was based on a positive RAST test and clinical history. The diagnosis was confirmed with a blinded controlled latex inhalation challenge test which resulted in a 39% drop in FEV1 and a trip to the ICU.

In light of my well-documented latex allergy, I'd like for you to consider the following as further incidents of reactions to consumer latex products to report to your CPSC databases. I think these 21 incidents will increase your numbers and you can count on them being legitimate and well documented since I am a physician. I've included episodes where I've had severe reactions after eating food which was handled with powdered latex gloves. The transfer of latex-powder has been well documented in the medical literature.

- 1/31/97 Latex balloon exposure at a Pizza Playland. Karen experienced bronchospasm and laryngospasm / anaphylaxis. She took her Epipen and called 911. At the Riverside ER they told her that they wanted to admit her to the hospital

for observation, but Karen said it was too dangerous for her to stay because of the latex aeroallergen in the hospital.

- 5/3/97 Karen had a severe asthma attack after eating at a restaurant. Her PF fell to 200 and her pulse was 170. An ER physician insisted that she come inside the ER for attention, despite Dr. Habbal's admonition in 3/97 for her not to enter Riverside Medical Center for any reason. She went to the **ER** and got a breathing treatment with oxygen, but she quickly left as she felt she was getting worse, not better. The Riverside ER was not "latex-safe" at this time.

- 1/26/98 ER visit. She experienced a severe asthma attack after eating a pre-packaged salad which may have been prepared by workers wearing powdered latex gloves. Her peak flow was unmeasurable initially. She was given emergency treatment including Solumedrol and **Epinephrine** in the allergy clinic for several hours, but then she worsened and was taken to the ER which was not yet completely latex-safe. She was discharged home as quickly as possible in order to reduce exposure to latex aero-allergen.
- But on 1/27/98 she returned to Baldwin Park ER after only a few hours at home. She again had **Epinephrine**. She was kept for observation in the ER. The Baldwin Park Medical Center had not yet opened its hospital for inpatient care and Riverside Medical Center was not yet latex-safe.

- 3/29/98 Asthma attack after exposure to latex balloons at a restaurant. **Epipen x 2**. Kept in Baldwin Park **ER** for 25 hours. Peak flow fell to 110, after the first shot of epi.

- 4/17/98 sudden severe asthma attack and laryngeal edema after eating Mueslix cereal. Peak flow went from 330 to 100 when measurable. **Epipen**. Baldwin Park **ER**. (Later Karen learned that the dried fruit is handled by workers wearing powdered latex gloves.)

- 6/5/98 Asthma attack due to latex balloon exposure at Kaiser's Regional OBGYN symposium. Peak flow went from 430 to 210.

- 7/18/98 Latex balloon exposure at a movie theater. Severe sudden asthma attack. Peak flow fell from 380 to 120. Spent 6 hours at Riverside **ER**.

- 7/29/98 Karen went to Riverside for ENT and Ophthalmology appointments. She was exposed to latex balloons in ophthalmology and developed shortness of breath. She then went to the pulmonary clinic for a breathing treatment. There she was exposed to powdered latex gloves. Her peak flow fell to 160. She then went to the Riverside **ER** for further treatment.

- 11/17/98 Exposed to latex balloons at a birthday party. Peak flow went from 420 to 190.

- 11/26/98 "Major ?anaphylactoid reaction" during Thanksgiving dinner after eating croissants. Peak flow fell from 390 to 130 when measurable. **Epipen.** Temecula was too far from a latex-safe Kaiser ER. Acute respiratory distress, throat closing, choking and vomiting.

- 12/19/98 Asthma attack. Peak flow fell from 480 to 180 after Karen stopped by to drop off a Christmas present at a friend's house. She was wearing powdered latex gloves to clean and took them off in front of Karen when she saw her.

- 4/19/99 Exposed to powdered latex gloves at daughter's school. Peak flow fell from 450 to 250.

- 9/1/99 Exposed to latex gloves at elementary school. Peak flow went from 350 to 190.

- 9/30/99 Exposed to latex balloons at physical therapy. Asthma attack. Peak flow went from 500 to 270.

- 5/23/01 severe asthma attack and GI distress after eating food which was handled with powdered latex gloves. (Learned of the latex-contamination after the fact.) Took **Epipen**. Went to **ER** at Baldwin Park.

- 8/9/01 Accidental exposure to powdered latex gloves by new housekeeper. Immediate asthma attack and runny nose followed the exposure and peak flow fell to 140. O2 Saturation 90%.

- 2/14/02 inadvertent exposure to latex balloons (Valentine-grams) when picking up daughter from school. Severe asthma attack / **anaphylaxis** with peak flows down to 130. Rash. Wheezing. Accessory muscle use. Used **Epipen**.911. **Admitted** to Fontana Medical Center 2/14/02- 2/15/02. Given IV Solumedrol 62 mg, plus IV Hydrocortisone 20 mg.

- 9/15/02 Exposed to latex during air travel. Became presyncopal, SOB, wheezing, sneezing, tachycardic, N/V. Took total of 65 mg Prednisone.
  Late September Karen developed increasing weakness.

- 12/14/02 Respiratory distress, asthma and rhinoconjunctivitis developed after an inadvertent exposure to latex balloon while attending her daughter's dance performance. (A child walked into the room and let go of a latex balloon which hit the ceiling fan and burst.) **Epipen.** Used continuous nebs and BiPAP to recover. Steroid burst followed by flare of steroid myopathy.

- 3/14/03 Acute asthma attack after exposure to latex balloons at a medical conference.

- **7/11/03** Asthma exacerbation treated at Riverside Medical Center **ER**. On 7/11/03 peak flow fell to 100 and FEV1 fell to 0.31 after exposure to latex balloons while at Riverside Medical Center. Tidal volumes in ER were initially 200's. ABG pO2 51/ pCO2 44/ pH 7.40/ HCO3 27/ O2 Sat 88%. Started Pulmicort Respules (nebulized budesonide) during acute flare plus Prednisone 20 mg burst.

To recap, I'd like to see CPSC take the following actions:

1. **Declare that natural rubber latex is a strong sensitizer.** There is good evidence of a high prevalence of latex allergy among individuals who are exposed to powdered latex gloves. CPSC should be concerned not with the incidence of latex allergy in the general public as a whole, but the incidence of latex allergy among the public who are exposed to powdered latex gloves. There is also good medical literature documenting the potential of severe reactions. There is no evidence that a consumer powdered latex glove used in food service is any safer than a medical powdered latex glove used in a hospital. And the death in England was reported to have occurred due to exposure to hair glue—a consumer product.

2. **Require labeling of all consumer products that contain natural rubber latex**— but especially consumer NRL gloves, latex balloons, Koosh balls, latex-resistive exercise bands, latex pacifiers and nipples, latex condoms, latex finger cots, latex-containing bandages/wraps, latex mattresses and pillows, and hair glue and other adhesives that contain latex which might contact the body.

3. **Take steps to reduce the latex allergen content and powder in consumer NRL gloves.** Preferably, powdered NRL gloves should be banned for consumer use and food service and non-medical occupations. But at a minimum, the CPSC should seek to apply the same standards that the FDA has proposed for medical NRL gloves. (Protein and powder limits, and warning labels.)

4. **Take steps to cause the manufacturers to reduce the latex allergen and powder content of latex balloons and latex resistive exercise bands.** Consider banning these products and encourage nonlatex alternatives such as Mylar balloons and nonlatex REP bands.

5. **CPSC should rule that latex foam mattresses and pillows cannot carry a claim to be "hypoallergenic".**

6. **CPSC should conduct a national campaign to educate the public on the risks of latex allergy.**

Sincerely Yours,

Karen Jakpor, MD, MPH

Vol 1
1E

January 9, 2004

From: Linda Shaw
107 Silverwood Lane
Cary, NC 27511
Fax: 919-859-6527

TO: Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207
Fax: 301-504-0127
RE: "Latex Petition Briefing"

To Whom It May Concern,
I am submitting comments in support of the petition to label consumer products containing natural rubber latex. The reason for this is that one of my sons has natural Rubber latex allergy which is due in part to the failure of companies to properly label product(s) to include all of the active and inactive ingredients in those products. If manufacturers want to produce products for the consumer(s) then each of the manufacturers and distributors should have no problem labeling what is in any products that is marketed to any consumer. If the product is safe, great, label it. Manufacturers must take responsibility and liability for products manufactured for consumer use.

If the product is not safe, label it. The label needs to carry a warning. All products containing natural rubber latex need to be labeled with a warning. It is not right to allow manufacturers to force the consumer to play Russian roulette with products on the market. I am not surprised that few consumers have time to write you. These consumers are constantly trying to deal with manufacturers that in many cases do not even call them back to tell them what is in their products. Families of and consumers that are allergic to natural rubber latex have been discriminated against due to manufacturers of natural rubber latex products refusing to follow safety guidelines in the processing and distributing of these products. When the manufacturers of the raw natural rubber latex stopped "leaching" or boiling the natural rubber latex when it comes off the tree, the protein then stays active and causes the unsuspecting consumer to become allergic to it. The protein in the milky sap of the natural rubber latex stays active. This is much like the concept that if you don't boil milk the bacteria in it stays active. Manufacturers of milk Pasteurize their product for the safety of their consumers. You would not serve your children milk that is not pasteurized. Yet, the American public is being served un-boiled natural rubber latex sticky sap that not only sensitizes the human body, but also Keeps live protein and probably live bacteria in it.

The general public pays the price. Over 18 million US citizens alone are now allergic to Natural Rubber Latex, and every day someone else becomes allergic to Natural Rubber latex. The statistics speak for themselves. This is why it is very important for the Consumer Product Safety Commission to make it mandatory that every manufacturer and distributor of any product containing Natural Rubber Latex label their products and also carry a warning label on their product(s).

Natural Rubber Latex needs to be added to the harmful ingredients list right along cigarettes and fireworks. Many children are unwittingly exposed to latex party balloons On an on-going basis by parents who have no clue as to what they are exposing their children to. Name one party decoration that is given out freely at grocery stores, restaurants, arenas that has a milky-sap that has un-boiled proteins in it and a substance That harbors bacteria. Name one party decoration that the general public has no idea that can harbor viruses and bacteria that spreads disease. Worried about the flu? Well, the flu isn't, because it has a great airborne passage way: the latex balloon. Worried about choking deaths? The latex balloon isn't because the Himelick maneuver does not work with it. Worried about this generation of kids? Well, schools in every State of the United States of America, are dealing with Natural Rubber Latex Allergy. I ask you, the Consumer Product Safety Commission to protect consumers who can not advocate for themselves and demand that all products that have natural rubber latex in them be labeled. Thank you.

Linda Shaw
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Fax: 919-859-6527

CC: Debi Adkins
Editor of Latex Allergy News

Abby Plambeck, RN, BSN
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Late 1/

FAX

Laura St. George
9237 W. Parkview Terrace Loop
Eagle River, Alaska 99577

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207

FAX#: 301-504-0127

January 9, 2004

To Whom It May Concern:

My eleven-year-old son was recently diagnosed with Natural Rubber Latex Allergy. Trying to determine which items have latex in them and which don't has been a nightmare. I have spent many hours and days on the internet emailing manufacturers and writing letters trying to determine the latex content of clothes and toys and school supplies and sports equipment and many other things that come in contact with my son.

Some companies have been very helpful and replied promptly. Other companies have not responded to emails or letters. Some customer service reps seem to honestly not know and not know who to ask because most of there manufacturing is done in various places overseas.

The only thing my son's allergist has told us we can do to help control this debilitating disease is to avoid latex. The lack of labeling legislation makes this a daunting task. Please help us out here and make it a law to label for natural rubber latex.

Fortunately, this is a fairly rare allergy, but it is on the upswing, especially in the health care industry workers. Labeling for latex would help us all avoid and control this horrible disease.

Sincerely,

Laura St. George

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CHIEF EXECUTIVE OFFICER

18

January 9, 2004

Suzanne Barone, PhD
Directorate of Health Sciences
U.S. Consumer Product Safety Commission
Washington, DC 20207

Dear Dr. Barone:

In response to the Federal Register notice titled, "Public Meeting Concerning Petition for Rule Declaring Natural Rubber Latex a Strong Sensitizer" (*Federal Register* Vol. 68, No. 220, 64610), the American Nurses Association (ANA) offers the following brief comment. The ANA appreciates the efforts to consider Petition HP 00-2 to declare natural rubber latex to be a strong sensitizer under the Federal Hazardous Substances Act. It is the ANA's intent to provide perspective that will help inform the Consumer Product Safety Commission's (CPSC) to fulfill its mission to protect the public from the risk of injury from consumer products.

Sensitivity to natural rubber latex has been well-recognized among healthcare workers, including nurses, physicians, dentists, and housekeeping and food service staff. Latex allergy affects between 8%-12% of workers in all health disciplines, though this range is likely to be a significant underestimate considering factors such as underreporting and misdiagnosis. In addition to healthcare workers, latex sensitivity is increasingly being observed among patient populations. Of particular note, up to 51% of children with spina bifida are affected with latex allergy. Considering previous reports and the continued extensive use of healthcare products and equipment made with rubber latex, the incidence of latex sensitivity among both healthcare workers and the general population may likely increase if not adequately addressed.

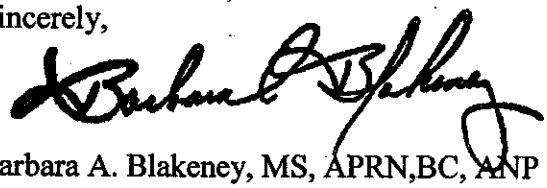
Reports reveal that types of latex-associated reactions range from irritant contact dermatitis (dry, itchy, irritated areas on the exposed skin areas), chemical sensitivity dermatitis (from exposure to chemical additives in latex products), and latex allergy (hypersensitivity resulting in mild allergic reactions to shock and death). Considering the continuum of the types and severity of reactions to latex products, any form of exposure must not be undervalued. Because there is currently no treatment for latex allergy, the ANA advocates for complete avoidance of latex products for those with sensitivity. Early diagnosis and latex avoidance are essential because continued exposure can lead to advanced allergic symptoms that disrupt careers and everyday living, and create serious barriers to health care. Sensitivity to latex products presents not only an occupational risk to healthcare workers, but also threatens their personal lives if exposed in settings outside the workplace. The burden on individuals with latex-sensitivity is immeasurable, particularly when considering their ability to pursue their chosen career, earn an income,

and deal with daily non-occupational activities. Countless numbers of nurses as well as other types of healthcare professionals are no longer employed in healthcare settings because the risk of exposure threatens their health and safety. This matter is particularly concerning in light of the well-documented nursing shortage that this nation's healthcare industry currently faces.

Recognizing both the prevalence and severity of latex sensitivity in healthcare settings, the U.S. Food and Drug Administration requires that medical devices containing natural rubber latex that contact humans, such as examination gloves, syringes, intravenous tubing, and condoms, be labeled informing users that exposure to such items may result in latex sensitivity. This intervention has allowed healthcare workers to avoid work-related exposure to latex-containing products and increased the level of awareness of the risk of developing latex sensitivity. Consistent with a proactive, preventive approach, the ANA believes that informing individuals through labeling is a minimal method to avert allergic, potentially life-threatening reactions. Many healthcare organizations, though, have gone even further by pursuing ways to achieve a "latex-free" environment both to keep affected employees and patients safe and to eliminate the potential development of latex-sensitivity.

Representing the interests of the 2.7 million Registered Nurses and advocating on behalf of the health and well-being of the public, the ANA believes that the CPSC should seriously consider the merits of Petition HP 00-2. The ubiquity of latex-containing products poses a true risk for numerous individuals both in and out of healthcare settings. Product labeling of latex content has contributed to the prevention of allergic reactions within the healthcare industry and can have an impact for society at large. The ANA thanks the CPSC for its work and looks forward to its ruling on this matter. Should you have any questions or concerns, please contact Dr. Butch de Castro at Bdecastro@ANA.org or (202) 651-7138.

Sincerely,



Barbara A. Blakeney, MS, APRN,BC, ANP
President

Enclosures

Position Statements

Latex Allergy

SUMMARY: Natural rubber latex allergy is a serious medical problem for a growing number of patients and a disabling occupational disease among health care workers. Latex allergy develops from exposure to natural rubber latex, a plant cytosol that is used extensively to manufacture medical gloves, other medical devices, and numerous consumer products. Allergic reactions to latex range from skin disease to asthma and anaphylaxis that can result in chronic illness, disability, career loss, hardship, and death. There is no treatment for latex allergy except complete avoidance of latex. Patients and health care providers must be assured safety from iatrogenic sensitization and allergic reactions to latex. Therefore, the American Nurses Association supports immediate interventions to reduce the risk of latex sensitization and ensure safe outcomes for latex-sensitized patients and personnel in all health care settings. Successful interventions will require collaboration between health care providers and administrators, with support from the research community, government agencies, manufacturers, professional organizations, sensitized patients, and patient advocacy groups.

Background

Delayed contact dermatitis from chemicals in rubber has been recognized since the 1930s.4 But except for rare early reports, clinicians did not appreciate systemic allergic reactions to latex proteins until 1979, when case reports began to appear in Europe. [5] Latex allergy erupted in the United States shortly after the Centers for Disease Control introduced universal precautions in 1987. By late 1992, the Food and Drug Administration (FDA) received 1133 reports of serious allergic reactions and anaphylaxis occurring to patients and health care staff associated with 30 classes of latex medical devices. There were 15 patient deaths associated with latex barium enema catheters.[5,6] The FDA estimated that the reports represented only 1% of actual occurrences.[6] Today, researchers hypothesize that the latex allergy outbreak is the result of multiple factors including deficiencies in manufacturing processes, increased latex exposure, hand care practices, immunological cross reactivity, and changes in latex agricultural practices.[1,7,8, 45]

Latex allergy affects between 8%-12% of workers in all health disciplines. Latex allergy also affects up to 51% of children with

spina bifida, and approximately 1% of the general population.

Definitions

Two types of allergies are associated with rubber: a) chemical contact dermatitis, and b) latex protein immediate hypersensitivity, which is termed latex allergy.

Chemical contact dermatitis is a delayed cell-mediated Type IV localized allergy that is caused by chemicals used to manufacture rubber products. The most common contact sensitizers are the accelerators: thiurams, mercaptobenzothiazols (MBTs), and carbamates.[1]

Latex allergy is a Type 1 IgE-mediated hypersensitivity reaction that involves systemic antibody formation to proteins in products made from natural rubber latex. Natural rubber latex is harvested commercially from the rubber tree, Hevea brasiliensis, and used to manufacture rubber products. Natural rubber latex contains up to 240 potentially allergenic protein fragments, and different persons may be sensitized to different combinations of latex allergens.[2] Synthetic latexes (e.g. synthetic latex paint or synthetic rubber) are not involved in latex allergy; therefore, this document refers only to natural rubber latex, henceforth termed latex.

Contact dermatitis, including both irritant and allergic responses, is the most common clinical reaction associated with the use of latex gloves. Irritant contact dermatitis is not an allergy.

Physiologic Effects, Diagnosis and Treatment

Latex exposure occurs through contact with the skin or mucous membrane, and by inhalation, ingestion, parenteral injection or wound inoculation. Data on the dose and duration of exposure, and the specific proteins required to produce sensitization are incomplete. Risk factors include occupational exposure to latex, multiple surgical procedures or mucosal instrumentation involving latex, and a personal or family history of allergies. Other unrecognized risk factors may exist.[16]

Latex sensitization causes skin disease, urticaria, angioedema, rhinoconjunctivitis, sinusitis, asthma, gastrointestinal symptoms, anaphylaxis and death.[8,19] Symptoms may present gradually and progress, although some individuals skip this progression and experience an abrupt onset of anaphylaxis or asthma.[19] Highly sensitized individuals can react to minute latex exposures.[7,19] Sensitized persons also may develop immunologic cross-reactivity

with fruits and vegetables that may have molecular structures analogous to latex, such as avocado, banana, European chestnut, the drupes (e.g., almond, cherry, peach, nectarine, etc.), kiwi, papaya, tomato, potato and others.[7,19,20]

There is no treatment for latex allergy except complete avoidance of latex, although eventually immunotherapy may become available.[12,21] Early diagnosis and latex avoidance are essential because continued exposure can lead to advanced allergic symptoms that disrupt careers and everyday living, and create serious barriers to health care.[19] Latex-sensitized persons should take the following precautions: a) avoid all contact with latex, b) carry auto-injectable epinephrine, and consult physicians for alternatives to beta blockers that are prescribed for other conditions, c) wear a medical identification bracelet, and d) negotiate with hospitals and providers in advance for latex-safe health and dental care. In turn, providers must be prepared to identify sensitized patients and deliver all levels of patient care, including emergency treatment, using nonlatex medical devices in an environment that is free of latex contamination.[19,22,23]

Medical Glove Allergenicity and Safe Use Practices

Latex medical gloves are the most prominent source of latex allergen exposure by cutaneous contact, inhalation, wound inoculation and ingestion.[27,48] Allergens levels vary considerably in gloves from different manufacturers, and from lot to lot, with higher levels occurring in powdered gloves and examination gloves than in powder-free gloves and surgical gloves.[24,27] Latex gloves that are inadequately processed during manufacture contain loosely-bound protein that readily rubs off or leaches into sweat, then accumulates on glove wearers' hands and easily transfers by touch to other persons and objects (e.g. medical records, telephones, doorknobs, food, etc.).[28] Therefore, it is essential that glove users wash their hands between glove changes and after removal, and avoid touching objects or latex-sensitized persons with latex gloves or unwashed hands.[4,28] Glove powder is a strategic factor in allergen exposure. Cornstarch donning powder actively extracts and binds protein from latex, which accumulates on glove wearers' hands, transfers onto objects, andaerosolizes.[28] Airborne particles of powder and protein may remain suspended for up to 5 hours, contaminating the air, ventilation system, skin, hair, clothing, wounds, and objects which can result in occupational asthma.[29,46] Therefore, health care providers must never use latex gloves in the care of latex-sensitized patients and must not use powdered latex gloves in general.[4,21,30,46,47] Low allergen, powder-free gloves decrease allergen exposure,[4,28,29,31,32] and also

reduce the incidence of allergic reactions and occupational asthma among sensitized workers.[4,21,33,34]

Glove-Associated Hand Dermatitis

Hand dermatitis, which is endemic among glove users, frequently is associated with occupational latex allergy.[35,36] Skin damage caused by dryness, irritation, contact dermatitis, or other dermatoses not only increases the risk of exposure to pathogens, but also may enhance absorption of glove chemicals and latex protein allergens.[7] Hand dermatitis may be a manifestation of either chemical contact dermatitis or latex allergy,[37] or co-existent contact dermatitis and latex allergy.[36] Therefore, glove wearers who develop hand dermatitis should seek early medical differential diagnosis that includes patch testing for glove chemical allergy, and latex allergy testing.[36,37] Although glove wearers with dermatitis commonly believe they are allergic to glove powder, sensitization to glove powder has never been shown conclusively.[37] Therefore, symptomatic persons should not delay in seeking differential diagnoses from physicians who are knowledgeable about glove-related allergies.

Glove wearers who use oil-based hand care products or medications to treat skin conditions increase their risk of exposure to allergens and microorganisms. Oil-based ingredients (e.g., jojoba, aloe vera, palm oil, coconut oil, lanolin, mineral oil, petrolatum products) degrade the molecular structure of latex and some synthetic glove materials within a few minutes, releasing protein and chemicals, and facilitating the passage of microorganisms.[4,38] Alternatively, water or glycerin-based hand care products are compatible with latex. Soaps, detergents, alcohol and various chemicals also degrade latex. Therefore, latex medical gloves are inappropriate for hospital housekeeping because they increase staff exposure to microorganisms and allergens,[39] and can contaminate the environment with allergens. Similarly, latex medical gloves are inappropriate for food service workers because they produce unnecessary risk for hand dermatitis and latex allergy, and may contaminate food with latex proteins, resulting in allergic reactions in sensitized persons.[40]

Glove Selection

Once a diagnosis of contact dermatitis or latex allergy is established, employers must provide gloves that are free of the causative agent.[41] Workers who have chemical contact dermatitis require gloves that have been sufficiently processed to remove the sensitizing chemical, and latex-sensitized persons must never wear latex gloves.[4,19,21,42]

The "hypoallergenic" label generally means that gloves are low in chemical contact sensitizers, but "hypoallergenic", does not refer to latex allergens in gloves.[1]

Recommendations

Therefore, the American Nurses Association recommends the following actions to protect patients and personnel from latex allergy in all health care settings:

1. Based on current research, all health care institutions should eliminate the unnecessary use of latex gloves and implement the use of low-allergen, powder-free latex gloves in all other settings.[3,46,47]
2. Each facility shall convene a multi-disciplinary latex allergy task force to develop patient care guidelines to:
    - ensure that the environment is free of contamination by latex and other substances carried by glove powder;
    - identify latex-sensitized patients and those at risk, instruct them about self-care, and deliver latex-safe care in accordance with recommended practice guidelines;
    - establish an inventory of nonlatex alternatives for latex medical devices;
    - develop procedures to identify and resolve problems with medical devices relevant to allergic reactions or glove performance;
    - report allergic events related to latex medical devices to the Food and Drug Administration MedWatch Program (phone 1-800-FDA-1088, Fax 1-800-FDA-0178).
3. Each health facility shall develop multi-disciplinary latex allergy occupational health guidelines that will:
    - ensure a workplace that is free of contamination by latex and other substances carried by glove powder;
    - educate personnel regarding latex allergy and related issues of hand care, hand dermatoses, glove use, product problem reports, and continued adherence to universal precautions;
    - provide task-appropriate, powder-free, low allergen gloves, and enlist manufacturers' support to resolve glove-related problems;
    - facilitate early identification, diagnosis, treatment and tracking of personnel with hand dermatoses or symptoms of latex allergy;
    - report allergic events related to latex medical devices to the Food and Drug Administration MedWatch Program (phone 1-800-FDA-1088, Fax 1-800-FDA-0178);
    - accommodate latex-sensitized employees safely in the workplace, assist disabled employees to obtain

rehabilitation services, and direct disabled personnel to compensatory benefits when rehabilitation is not possible.

4. All health personnel shall:
   - be knowledgeable of latex allergy and its related issues;
   - implement latex allergy guidelines pertaining to the safety of patients and staff;
   - seek occupational health services and medical care for early diagnosis and treatment of hand dermatoses and symptoms suggestive of latex allergy and request documentation of glove-associated illness to OSHA;
   - report allergic events related to latex medical devices to the Food and Drug Administration MedWatch Program (phone 1-800-FDA-1088, Fax 1-800-FDA-0178);
   - be knowledgeable about employees' rights to workplace safety, reasonable accommodations for latex-sensitized personnel to remain employed, rehabilitation services, and compensatory benefits for disability when rehabilitation is not possible.

Effective Date: September 15, 1997
Status: Position Statement
Originated by: Congress on Nursing Economics
Adopted by: ANA Board of Directors

Related Past Actions:
1995 - Hazardous Workplace Air Quality
1994 - Risk Versus Responsibility in Providing Nursing Care
1993 - Health and Safety in the Workplace
1984 - Employees Right to Know Hazards in the Workplace
1982 - Health Hazards in the Workplace

Footnotes

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Other Resources

- ANA Department of Labor Relations & Workplace Advocacy: Occupational Safety and Health Concerns | latex allergy
- Safety & Quality Intiatives Introduced by State Nurses Associations

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Federal Register: Natural Rubber-Containing Medical Devices; User Labeling

[Federal Register: September 30, 1997 (Volume 62, Number 189)]

[Rules and Regulations]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0119]

21 CFR Part 801

Natural Rubber-Containing Medical Devices; User Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule requiring labeling statements on **medical devices**, including device packaging **containing natural rubber** that contacts humans. The rule requires labeling of **medical devices containing natural rubber** latex that contacts humans to state: ``Caution: This Product Contains **Natural Rubber** Latex Which May Cause Allergic Reactions.''; labeling of **medical devices containing** dry **natural rubber** that contacts humans to state: ``This Product Contains Dry **Natural Rubber.**''; labeling of **medical devices containing natural rubber** latex in their packaging that contacts humans to state: ``Caution: The Packaging of This Product Contains **Natural Rubber** Latex Which May Cause Allergic Reactions.''; labeling of **medical devices containing** dry **natural rubber** in their packaging that contacts humans to state: ``The Packaging of This Product Contains Dry **Natural Rubber.**''; and that the claim of hypoallergenicity be removed from the labeling of **medical devices** that contain **natural rubber**. These requirements are being established in response to numerous reports of severe allergic reactions and deaths related to a wide range of **medical devices containing natural rubber**.

EFFECTIVE DATE: This final rule is effective September 30, 1998.

FOR FURTHER INFORMATION CONTACT: Donald E. Marlowe, Center for **Devices** and Radiological Health (HFZ-100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850, 301-443-2444, FAX 301-443-2296.

SUPPLEMENTARY INFORMATION:

I. Background

Natural latex is a milky fluid obtained in commercial quantities

primarily from the Heavea brasiliensis (**rubber**) tree. There is often confusion concerning the terminology used to describe the raw agricultural materials derived from **rubber**-producing plants; products made from various intermediate forms of the

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raw agricultural material (e.g., **natural rubber** latex, dry **natural rubber**); formulations of synthetic latex and synthetic **rubber** to which **natural rubber** has been added; and synthetic **rubber** and synthetic latex formulations that do not contain **natural rubber**.

``**Natural** latex,'' for the purposes of this rule, is defined as a milky fluid that consists of extremely small particles of **rubber** obtained from plants, principally from the H. brasiliensis (**rubber**) tree, dispersed in an aqueous medium. It contains a variety of naturally occurring substances, including cis-1,4-polyisoprene in a colloidal suspension (Ref. 1) and plant proteins, which are believed to be the primary allergen (Refs. 2, 3, and 4).

``**Natural rubber**,'' for the purposes of this rule, includes all materials made from or **containing natural** latex. Products that contain **natural rubber** are made using two commonly employed manufacturing processes, the **natural rubber** latex (NRL) process, and the dry **natural rubber** (DNR) process.

The NRL manufacturing process involves the use of **natural** latex in a concentrated colloidal suspension. Products are formed from **natural rubber** latex by dipping, extruding, or coating, and are typically referred to as **containing** or made of ``**natural rubber** latex.'' Examples of products that may contain **natural rubber** latex include **medical** gloves, catheters, tracheostomy tubes, and condoms.

The DNR manufacturing process involves the use of coagulated

natural latex in the form of dried or milled sheets. Products are formed from dry **natural rubber** by compression molding, extrusion, or by converting the sheets into a solution for dipping. These products are typically referred to as **containing** or made of dry **natural rubber** or ``crepe'' **rubber**. Examples of products that may contain dry **natural rubber** include syringe plungers, vial stoppers, and injection ports on intravascular tubing.

The phrase, ``contains **natural rubber**,'' as used herein, also includes products described as made of ``synthetic latex'' or ``synthetic **rubber**'' that include **natural rubber** in their formulations. This rule does not apply to products made from synthetic latex or synthetic **rubber** that do not include **natural rubber** in their formulations.

FDA has noted an increase in the number of reports submitted to its **medical** device reporting system regarding sensitivity to **natural** latex proteins contained in **medical devices**, including deaths following barium enemas. These deaths were associated with anaphylactic reactions to the **natural rubber** latex cuff on the tip of barium enema catheters. Scientific studies and case reports have documented sensitivity to **natural** latex proteins found in a wide range of **medical devices** (see Refs. 2 through 23).

Based upon this information, the agency published a proposed rule on June 24, 1996 (61 FR 32618), to require labeling statements on **medical devices containing natural rubber** that contact humans. This final rule is based upon comments submitted in response to the June 24, 1996 proposed rule.

II. Highlights of the Final Rule

A. **Natural Rubber-Containing Devices**; Labeling

FDA is requiring the labeling for **medical devices containing natural rubber** that contacts humans to include a statement regarding the presence of **natural rubber**. The agency is issuing this rule because **medical devices** composed of **natural rubber**, or which contain components formulated from **natural rubber**, may pose a significant health risk to some consumers or health care providers who are sensitized to **natural** latex proteins. A statement in the labeling of **medical devices** identifying the presence of **natural rubber** latex is considered to be necessary for the safe and effective use of such **devices**.

``Contacts humans,'' for the purposes of this rule, means that the **natural rubber** contained in a **medical** device is intended to contact or is likely to contact the user or patient. This includes contact when the **natural rubber containing** device is connected to the patient by a liquid path or an enclosed gas path; or the **natural rubber containing** device is powdered, and the powder may carry **natural** latex proteins that may contaminate the environment of the user or patient.

The device may bear one or more of four labeling statements depending on the type of **natural rubber** in the device and depending on whether the **natural rubber** is in the device itself or in its packaging. The reasoning for requiring one or more of four separate statements is discussed more fully in comments 3 and 6 in section III of this document.

Medical devices containing rubber produced by the NRL process that contacts humans shall bear labeling with the following statement in bold print: ``Caution: This Product Contains **Natural Rubber** Latex Which May Cause Allergic Reactions.'' Representative examples of **devices** that contain NRL include: Cuffed enema/enterolysis catheters, latex condoms (with or without spermicidal lubricant), wound drains, cuffed airways, latex surgical gloves, and latex examination gloves.

The agency is also requiring that **medical devices containing rubber** produced by the DNR process that contacts humans include the following statement in bold print in their labeling: ``This Product Contains Dry **Natural Rubber**.'' Representative examples of **devices** that contain DNR include: Anesthesia masks, electrode pads, contraceptive diaphragms, crutch pads and tips, wheelchair tires, elastic components of bandages/ face masks, syringe plungers, parenteral drug vial stoppers, and intravenous injection ports.

The agency is further requiring **medical devices** having packaging that contains **natural rubber** that contacts humans bear labeling with one of the following statements in bold print: ``Caution: The Packaging of This Product Contains **Natural Rubber** Latex Which May Cause Allergic Reactions.'' or ``The Packaging of This Product Contains Dry **Natural Rubber**.'', as appropriate. The purpose of such statements is to inform individuals who are sensitive to **natural rubber** about the presence of **natural rubber** in the packaging of **devices** that may be, by themselves, **natural rubber**-free.

B. Hypoallergenicity

FDA believes that it is also necessary to prohibit certain labeling statements on **medical devices** that contain **natural rubber**. FDA believes that the labeling statement ``hypoallergenic,'' traditionally used with respect to **medical** gloves, cosmetics, and other products produced for individuals with chemical allergies, is interpreted by consumers to mean that the risk of allergic reactions to any component of the device would be minimal. This is not the case with **devices** that contain **natural rubber**. FDA has received reports of allergic reactions to **medical** gloves labeled as ``hypoallergenic.''

Use of the ``hypoallergenic'' label has been based on results of

the modified (human) Draize test. While this test may be appropriate for detecting sensitization to residual levels of processing chemicals, the test does not detect sensitivity to **natural** latex proteins.

Thus, there is no reasonable assurance that the risk of allergic reactions to products that contain **natural rubber**, yet have reduced levels of processing chemicals, will be reduced for individuals who are sensitive to **natural** latex proteins. Therefore, the agency believes that the term ``hypoallergenic'' on the labeling of a device that contains **natural rubber** is misleading in that it

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incorrectly implies that such device may be used safely by persons sensitive to **natural** latex proteins. For these reasons, FDA is requiring that the hypoallergenic claim be removed from the labeling of **devices** that contain **natural rubber**.

C. Effects of This Regulation on Premarket Submission Requirements

FDA will not require a new submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) based upon labeling changes made to comply with this rule, provided that no other changes requiring a new 510(k) submission under 21 CFR 807.81 are made to the device. **Devices** subject to an approved premarket approval application, however, must submit any change to the device labeling that is required by this rule in the next interim report under 21 CFR 814.39(e). Combination products that have device and drug components but are regulated under drug premarket approval provisions shall indicate the labeling change in a supplement for changes that may be made before FDA approval, as required by 21 CFR 314.70(c). Combination

products that have device and biological components, but that are regulated under the biologic premarket approval provisions, shall inform the agency of the labeling change in the manner described under 21 CFR 601.12.

III. Summary of Comments

The agency received 62 comments, all of which supported the principle of **natural rubber** labeling for the protection of **natural rubber** sensitive individuals. The comments, however, differed greatly in their specific approaches.

1. A few comments suggested using the term ``crepe **rubber**,'' instead of ``dry **rubber**,'' and suggested using the term ``synthetic **rubber**'' instead of ``synthetic latex.''

The agency agrees that ``synthetic **rubber**'' should be used to describe components of certain **natural rubber** products covered by this regulation and has added that term in the definition of ``**natural rubber**'' in Sec. 801.437(b) (21 CFR 801.437(b)). Although the agency has discussed the meaning of crepe **rubber** in the preamble to this regulation, the agency does not agree that the term ``crepe **rubber**'' should be used in place of ``dry **natural rubber**'' in the regulation because the agency believes the term ``dry **natural rubber**'' is the term most commonly used to describe **rubber** manufactured by the DNR process.

2. One comment pointed out that there are other sources of **natural rubber** besides that identified in the preamble of the proposed rule, the H. brasiliensis tree.

The agency agrees and has clarified in the preamble of this regulation that there are other sources of plant-derived **natural rubber** used in the manufacture of **devices** that are subject to this rule. The preamble notes that the H. brasiliensis tree is the primary source of

commercial **natural** latex, instead of the only source.

3. Several comments claimed that there is no information to suggest that dry **natural rubber** has caused allergic reactions in individuals sensitive to **natural** latex proteins; therefore, dry **natural rubber** should not be included in the labeling requirement.

The agency recognizes that there are lower levels of **natural** latex proteins in products produced by the dry **natural rubber** process. The agency, however, does not agree that there is no information to suggest that dry **natural rubber** has caused allergic reactions in individuals sensitive to **natural** latex proteins. To the contrary, there are numerous reports that levels of **natural** latex proteins found in dry **rubber** can cause allergic reactions (Refs. 24 through 27). Accordingly, the agency has concluded that it is in the best interest of the public health to provide labeling information that a product contains dry **natural rubber**, so that individuals who are sensitive to the levels of **natural** latex proteins found in dry **natural rubber** may make an informed decision regarding the use of the product.

While the agency believes that persons who may respond to the levels of **natural** latex proteins found in dry **natural rubber** need to be informed of the dry **rubber** content in a device, the agency does not believe that those individuals need to be informed of the health consequences associated with dry **natural rubber**. Because allergy is a dose-response phenomenon, persons who may react to **natural** latex protein levels found in dry **rubber** would have already experienced previous allergic reactions to the higher levels of **natural** latex proteins found in **natural rubber** latex products (see Ref. 28). Therefore, those individuals would generally be aware that dry **natural rubber** may cause them to suffer an allergic reaction. Accordingly, FDA is requiring that products that contain only dry **rubber** have labeling that informs consumers of the dry **rubber** content, but is not requiring

that such products bear labeling that states the potential health consequences from the use of the product. Therefore, FDA is requiring in the final regulation, Sec. 801.437(e), that **devices** that contain dry **natural rubber** bear labeling with the following statement: ``This Product Contains Dry **Natural Rubber**.''

Persons who would not react to the levels of **natural** latex proteins found in dry **rubber**, but would react to the higher levels of **natural** latex proteins found in **natural rubber** latex products, however, may never have been aware of previous allergic reactions (Ref. 28). These persons, therefore, need to be advised of the potential health consequences of **natural rubber** latex products. Accordingly, FDA is requiring products **containing natural rubber** latex to carry labeling that states the potential health consequences of such products, as well as a **natural rubber** latex content statement. Therefore, FDA is requiring in the final regulation, Sec. 801.437(d), that **devices containing natural rubber** latex have labeling with the following statement in bold print: ``Caution: This Product Contains **Natural Rubber** Latex Which May Cause Allergic Reactions.''

This statement is also required if a device contains both **natural rubber** latex and dry **natural rubber** that may contact humans. In this instance, the single statement will serve to advise a person who may not be aware that **natural rubber** may cause reactions, and will also advise a person who is aware of his or her sensitivity to **natural rubber** that the product contains an ingredient that may cause a reaction.

4. Some comments claimed that the applicability of the labeling statement to **devices** that contain **natural rubber** ``that may directly or indirectly contact humans'' is overly broad. One comment suggested that the labeling statement be required only on **devices** that have an ``intended use'' that may lead to contact with humans. Other comments

suggested the statement be limited to **devices** which would directly contact tissues.

The agency does not believe that the application of the labeling statement to **devices** that contain **natural rubber** ``that may directly or indirectly contact humans'' is overly broad. Latex proteins may elicit an allergic reaction in individuals who are sensitive to **natural rubber**, even if the proteins are introduced to the individual through an indirect route. The agency, however, recognizes that the term ``indirect contact'' may be interpreted more broadly than the agency intends. Therefore, in order to avoid confusion, the agency has modified the regulation to require the labeling statements only if the **natural rubber** contacts humans. The final regulation, Sec. 801.437(b), defines the term ``contacts humans'' to mean that the **natural rubber** contained

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in a device is intended to contact or is likely to contact the user or patient (e.g., latex **medical** gloves or latex enema tips). This includes contact when the device that contains **natural rubber** is connected to the patient by a liquid path or an enclosed gas path (e.g., intervenous administration sets, or blood collection or transfusion tubing with **natural rubber** injection ports, injection syringes with **natural rubber** plungers, or **natural rubber** tubing or connector components used in anesthesia or endoscopic insufflator circuits). This also includes contact when the device that contains **natural rubber** is fully or partially coated with a powder, and such powder may carry **natural rubber** proteins that may contaminate the environment of the user or patient (e.g., latex tourniquets). This definition makes it clear that the labeling statement is required on **devices** that have an intended use

that could reasonably be expected to introduce **natural** latex proteins to humans.

5. Several comments suggested that the **natural rubber** labeling statement be expanded to apply to nonmedical **natural rubber** latex gloves and other consumer products that contain **natural rubber**. Other comments suggested that **medical devices** sold over-the-counter (OTC) to the consumer be exempt from the labeling requirements in order to avoid confusion regarding the **natural rubber**-content of other consumer goods that would not be subject to this labeling regulation.

The agency disagrees that the regulation should apply to nonmedical **natural rubber** latex gloves and other consumer products that contain **natural rubber**. The regulation of such products is beyond the scope of this rule. FDA's authority under the act to impose labeling requirements is restricted to products that meet the definition of foods, drugs, cosmetics, animal drugs, biologics, and **devices**, as those terms are defined under the act. This rule applies to **devices** as defined under section 201(h) of the act (21 U.S.C. 321(h)). Under section 201(h) of the act, a device is:

* * * an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is * * * intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals * * *, and which does not achieve any of its principle intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Latex gloves and other products are subject to this rule, only if they meet the definition of device under section 201(h) of the act. Latex gloves that are not used in the cure, mitigation, treatment or

prevention of disease are not **devices** within the meaning of section 201(h) of the act, and, therefore, are not subject to this rule. Latex **medical** gloves that are subject to this regulation include surgeon's gloves, as classified at 21 CFR 878.4460, and patient examination gloves, as classified at 21 CFR 880.6250.

FDA also does not agree with the suggestion that OTC **medical devices** be exempted from the labeling requirements in order to avoid confusion with **natural rubber** products that are not subject to this rule. The purpose of the labeling requirement is to provide essential information for individuals sensitive to **natural** latex proteins. An individual who is sensitive to **natural** latex proteins is equally likely to react to an OTC device that contains **natural rubber**, as to a prescription device that contains **natural rubber**. Therefore, it is equally important to provide essential information about OTC **devices** that contain **natural rubber**, as it is to provide information about prescription **devices** that contain **natural rubber**. Moreover, the agency does not believe that labeling, as required by this rule, on OTC **devices**, will cause significant confusion regarding the **natural rubber** content of consumer products that are not **devices**.

6. Several comments requested clarification on the applicability of the requirements to certain **devices**. Specifically, the comments asked whether the rule would apply to: Bandages with **natural rubber** in the adhesive; **natural rubber**-free **devices** packaged in a wrapper using **natural rubber** in the adhesive, especially where the adhesive would contact human tissue while unwrapping the device; foods or **natural rubber**-free **devices** handled or applied with **natural rubber** latex gloves; covered elastic stretch bands used to attach an accessory or component to a device; or, **devices** intended to contact only subcutaneous tissue.

A labeling statement is required for **devices** that contain **natural**

rubber when the **natural rubber** contacts humans, as described in Sec. 801.437(b) of the final rule. Accordingly, **devices** intended to contact subcutaneous tissue would be required to bear the appropriate statement.

Moreover, bandages with **natural rubber** in the adhesive would require the labeling statement. For this product, the **natural rubber** is intended to be applied directly to the skin. If **natural rubber-containing** adhesives in tapes, bindings, and similar items are intended to contact, or are likely to contact, the user or the patient, they are required to be labeled under this regulation. Covered elastic bands would not be considered to be in contact with humans, provided the covering blocks the migration of **natural rubber** proteins to the patient and user.

FDA does not believe it would be appropriate to require **natural rubber** labeling statements for **natural rubber**-free **devices** or foods that may be handled with latex gloves. As described previously in comment 5 of this document, requiring **natural rubber** labeling for products, such as foods, that are not **devices** is beyond the scope of this regulation. Moreover, FDA does not believe that requiring products that are handled by latex gloves, regardless of whether such products could be within the scope of this regulation as **devices**, is appropriate if such products do not contain **natural rubber**. Requiring labeling on products that may or may not come into contact with latex gloves would confuse consumers and would be impracticable to implement. Furthermore, FDA is not aware of any reports of allergic reactions to **rubber**-free products that latex gloves have contacted.

Under the final rule, **natural rubber-containing** packaging adhesives that typically are in areas that hold the flaps of packaging together would meet the criteria to subject the product to this rule only if they contact the patient or user. However, the agency is not aware of

any evidence or reports of reactions to packaging adhesives. Given the pervasiveness of the use of adhesives that contain some amount of **natural rubber** latex, the lack of evidence that these adhesives cause adverse reactions, and the ability to open packaging with adhesives without coming into contact with the adhesives, the agency concludes that the adhesives in device packaging are not intended to contact humans and are not likely to contact humans. Therefore, if such adhesives are the sole source of **natural rubber** in the device packaging or the device itself, a device with such packaging would not be subject to this rule.

The agency stresses, however, that it considers device packaging to be an integral part of a device. Under section 201(h) of the act, a device includes any components, parts, or accessories. As an accessory to a device, the packaging is a device under section 201(h) of the act. A device that contains **natural rubber** in

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its packaging, beyond that found in the adhesive (e.g., a device packaged in a latex sheath) is likely to contact the user or patient and must be labeled as **containing natural rubber**.

In order to avoid confusion and to clarify to the consumer whether it is the device itself or its packaging that contains **natural rubber**, however, the agency believes that a distinct labeling statement is appropriate for **devices** that have packaging that contains **natural rubber** that contacts humans. Accordingly, under Sec. 801.437(f) and (g) of the final regulation, such **devices** shall have labeling with one of the following statements: ``Caution: The Packaging of This Product Contains **Natural Rubber** Latex Which May Cause Allergic Reactions.'' or ``The Packaging of This Product Contains Dry **Natural Rubber**.''

The agency notes that if one of these packaging statements is required, it shall appear regardless of whether there is a **natural rubber** statement relating to the product itself. For example, a device that contains dry **natural rubber** that contacts humans and is also packaged in dry **natural rubber** that contacts humans shall be labeled with both the statements: ``Caution: The Packaging of This Product Contains Dry **Natural Rubber**.'' and ``This Product Contains Dry **Natural Rubber**.''

7. Several comments suggested that the labeling statements be required only on finished **medical devices**, and that device components be exempt.

The agency agrees in part. The regulation applies to all finished **devices** and components that are intended to contact or are likely to contact the user or patient. The labeling statement does not apply to components shipped directly to a manufacturer or processor for use in the manufacture of a device because these components, during the time before distribution to consumers, would not be intended to contact, or likely to contact the user or patient. Under these circumstances, the parts or components are not accessible to health care workers or patients. If, however, a device component is sold directly to a consumer, including a patient or health care worker, and it is intended to contact or likely to contact a user or patient, it is required to be labeled under this regulation, regardless of whether it must be attached, inserted, or used in conjunction with other **devices**. Replacement parts marketed as accessories for **medical devices** that are intended to contact or likely to contact a user or patient also require the labeling statement.

8. One comment suggested that in vitro diagnostic **devices** be exempt because only dry **natural rubber** is used, there is usually no patient contact with the **natural rubber** components, and space is very limited

for labeling. One comment suggested that other **devices** that do not contact the patient be exempted, regardless of whether the **natural rubber** contacts the tissues of the health care worker.

The agency believes that in vitro diagnostic **devices** should be exempt only to the extent that the **natural rubber** used in vitro diagnostic **devices** is not intended to contact or is not likely to contact the user or the patient. FDA, however, is requiring labeling for such **devices** if they are intended to contact or are likely to contact health care workers or other users, as well as the patient, because all latex-sensitive persons who use the device need to be informed of the product's **natural rubber** content.

9. One comment requested an exemption for the labeling of **natural rubber** latex condoms because such condoms clearly contain latex. The comment also believed an exemption should apply to latex condoms because space for labeling is limited, a warning regarding allergic reactions may have a chilling effect on the use by individuals who are not sensitive to **natural rubber**, and the statement may lead to confusion in differentiating between latex and **natural** skin condoms because **natural** skin condoms also contain some **natural rubber** latex and would require the statement as well.

The agency disagrees and will require latex condoms to bear a labeling statement that the product contains **natural rubber** latex that may cause allergic reactions. Even though consumers may be aware that the product contains latex, FDA believes that the additional information that **natural rubber** latex may cause allergic reactions is essential information to individuals who are not aware that **natural rubber** latex may cause allergic reactions. The agency believes that there is sufficient room on condom packaging for the required statement.

FDA does not believe that the statement will have a chilling effect

on the use of condoms by individuals who are not sensitive to **natural** latex proteins. The statement, however, would clearly provide important information to individuals who are sensitive to **natural** latex proteins.

The agency further disagrees with the suggestion that the labeling statement would be required on **natural** skin condoms, and thereby confuse consumers with respect to the differences between latex and **natural** skin condoms. Although **natural** skin condoms do contain a **natural rubber** elastic band, this band is wrapped within the **natural** skin sheath, and there is no evidence to indicate that the **natural rubber** ever contacts the user. Therefore, **natural** skin condoms that have a latex component that is not intended to contact or likely to contact the user do not require the labeling statement. Accordingly, the absence of any latex labeling requirement for **natural** skin condoms obviates the comments concern about confusion that may result from latex labeling statements on both latex and **natural** skin condoms.

10. Although most comments supported the requirements of standard labeling requirements, some comments suggested that the proposed labeling statements were overly prescriptive, and that manufacturers should have wide latitude in the wording of the statement provided it contain a general latex ingredient statement. Other comments stated that the labeling statements did not provide sufficient warnings, and suggested that the agency require a caution stating that use of the device may lead to chronic asthma, dermatitis, or even anaphylactic shock and death.

The agency does not agree with comments suggesting the labeling should state possible reactions with specificity. FDA believes that the statement advising consumers that a product may cause an allergic reaction is specific enough to provide adequate warning.

The agency also does not believe that the required labeling statements are overly prescriptive and that manufacturers should be

given wide latitude in the wording of labeling statements. The agency has determined that requiring standardized statements for **devices containing natural rubber** is the best approach for providing the essential information in a clear, consistent, and accurate manner.

FDA realizes that there may be some circumstances where it may be appropriate to tailor specific information concerning a device. If a manufacturer believes use of statements that vary from those prescribed by this regulation is appropriate, Sec. 801.437(i) of the final regulation provides that the manufacturer may petition the agency for an exemption or variance from these requirements by submitting a citizen petition under 21 CFR 10.30. Unless the agency has specifically granted an exemption or variance, the agency will consider any variation from the required statement to be noncompliant, and the device will be deemed misbranded.

11. Several comments suggested that the agency recommend the use of

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natural rubber-free **devices**, or require a labeling statement that nonnatural **rubber** alternatives are available. In contrast, some comments supported **natural rubber** labeling provided that the label be ``ergonomically equitable'' (sic) (i.e., not giving **natural rubber**-free **devices** a perceived advantage).

The agency does not recommend the use of one legally marketed device over another. Rather the agency is requiring that labeling for **devices** that contain **natural rubber** provide information upon which an individual may make an informed choice regarding the use of the device. The benefits of **devices** that contain **natural rubber** are well established, and the agency does not intend to discourage their use by persons who are not sensitive to **natural rubber**. Therefore, the agency

will not require the labeling statement to recommend the use of **rubber**-free **devices**.

Furthermore, because the agency is not requiring a statement that recommends the use of **natural rubber**-free **devices**, the agency does not believe that this rule gives **natural rubber**-free **devices** an advantage over **devices** that contain **rubber**. Accordingly, the agency does not believe that further modifications to the required statements are necessary to address comments that suggested the labeling not give the impression that **natural rubber**-free products have an advantage over products that contain **natural rubber**.

12. One comment requested clarification on the labeling of combination products consisting of drugs that are packaged in device container vials with dry **natural rubber** stoppers.

This final regulation provides authority to require **natural rubber** labeling on all **devices containing natural rubber**, including **devices** that are contained within combination products. As discussed in more detail in this comment, FDA intends to apply the **natural rubber** labeling requirement to combination products, such as drugs in device containers that are regulated currently under drug authorities.

In a final rule that published in the Federal Register of November 21, 1991 (56 FR 58754), the agency explained that ``the term combination product means a product comprised of two or more different regulated entities, e.g., drug, device, or biologic * * *'' or two or more different regulated entities that are produced together as a single entity, packaged together, or used together to achieve the intended effect (see 21 CFR 3.2(e)). The fact that a single product contains two or more regulated entities does not in itself change the regulatory status of the individual entities.

Because the entities that comprise a combination product meet more than one jurisdictional definition, the agency may apply one or more

sets of regulatory provisions to the product. The agency, for example, has applied both drug and device authorities, and both biological and device authorities, to certain combination products. (See Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for **Devices** and Radiological Health (the Drug/Device Agreement (Ref. 29)), and Intercenter Agreement Between the Center for Biologics Evaluation and Research and the Center for **Devices** and Radiological Health (the Biologics/Device Agreement (Ref. 30)) (hereinafter referred to collectively as the Intercenter Agreements).)

Device container vials with dry **natural rubber** stoppers, when used in combination with a drug product, may be subject to regulation under the statutes and regulations applicable to **devices**. A vial that has a **natural rubber** stopper meets the definition of a device under section 201(h) of the act, in that such vial is ``an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or some other similar or related article, including any component, part, or accessory * * *'' that is intended to cure, mitigate, treat, or prevent disease, which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The agency regulates these empty vials, as well as other empty drug or biologic containers (such as stoppered vials for use in blood collection, intravenous containers, and blood bags), as **devices**.

When the drug is contained in a vial, however, the result is a combination product. The combination status of **devices** that serve as containers for drugs is specifically recognized in the Drug/Device Agreement. (See Ref. 29, p. 14.) To date, these combination products have been regulated only under the drug authorities (Id).

The agency intends to require that all combination products that

contain **natural rubber** device components be labeled in accordance with this regulation. Although the agency could require all combination **natural rubber** products to comply with the regulation on its effective date, this regulation will be applied as follows: **Natural rubber** combination products that are currently listed in the Intercenter Agreements as being regulated under device labeling provisions will be required to comply with this rule on its effective date; **natural rubber** combination products that are listed in the Intercenter Agreements as being regulated under drug or biologic labeling provisions, however, will be subject to this regulation at the time of the effective date of this regulation, or at the time the Intercenter Agreements are amended to provide that these types of combination products are subject to this labeling regulation, whichever is later. FDA will provide notice in the Federal Register of the amendments to the Intercenter Agreements to apply this **natural rubber** labeling provision to all combination products that contain **natural rubber** device components.

At this time, the agency anticipates that the Drug/Device Intercenter Agreement will be amended to reflect that prefilled drug vial containers, transdermal patches, infusion pumps, and prefilled syringes that presently are regulated under drug authorities are also subject to this regulation. The agency believes, however, that this requirement will not affect many drug vial containers, because most drug stoppers are not being manufactured from dry **natural rubber**.

13. A few comments requested clarification on the applicability of the requirements to **devices** already in the marketplace or intended solely for export.

This rule is not intended to require manufacturers to recall any **devices** already in interstate commerce. Therefore, this rule does not apply to **devices** initially introduced or initially delivered for introduction into interstate commerce before the effective date of this

regulation.

Devices intended solely for export will not be deemed misbranded for failure to comply with this regulation provided that the exporter meets the criteria of sections 801(e) and 802 of the act (21 U.S.C. 381(e) and 382). Nevertheless, FDA encourages the application of a **natural rubber** content statement to all exported **devices containing natural rubber** that may contact humans.

14. A few comments suggested that **devices containing** less than a minimum quantity of **natural rubber**, the amount to be determined by the agency, be exempt from the labeling requirement. One comment suggested that **devices** be labeled with the extractable **natural** latex protein content.

The agency agrees in principle, however, insufficient information currently exists regarding the minimum

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amount of extractable **natural** latex protein that would not elicit an allergic reaction for this option to be practicable. Evidence indicates that some persons are reactive to extremely low levels of proteins (Ref. 31). The agency is unable to determine what minimum amount of **natural** latex proteins fails to elicit a reaction in some individuals, and, therefore, cannot exempt **devices containing** less than that minimum.

15. Several comments requested clarification on the level of packaging that would require a labeling statement. Some comments requested additional flexibility in the placement of the statement so that the statement may be put on the device labeling other than the label, especially where the device label may be too small to carry such a statement. Another comment recommended that the statement be required

not only on the label and in other labeling, but on the device itself if the device is dispensed in bulk, as in the case with **natural rubber** latex examination gloves. Other comments suggested that bulk **devices** either remain in the original package in order to preserve the label, or that the agency require the user facility to educate and monitor the use of bulk **devices containing natural rubber**. Still another comment suggested that where bulk **devices** are removed to a separate dispensing container, the dispensing container also be required to be labeled with a **natural rubber** content statement.

FDA believes that the required labeling statements may be fitted on small labels. Because of the importance of the information contained in the labeling statements for individuals sensitive to **natural** latex proteins, the agency will require the appropriate statements concerning the **natural rubber** content of the products to be prominently and legibly displayed on all device labels, and other labeling, and to appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

This means, for example, that the labeling statement for adhesive bandages that are individually wrapped and sold in a box would appear on each individually wrapped bandage, on the box, and on any individual pieces of labeling, such as an instructions for use sheet included in the box. **Devices** packaged and sold in bulk dispensing containers would be required to display the appropriate statement on the dispensing container, as it is the immediate device container or package.

If the packaging of a device contains **natural rubber**, the final regulation requires that a separate statement that specifically cautions the user that the **natural rubber** is contained in the packaging itself. Statements relating to the **natural rubber** content of the packaging do not have to appear on the same levels of labeling as the

cautionary statements relating to **natural rubber** content in the actual product. The statements cautioning the user that the packaging contains **natural rubber** shall appear, instead, only on the packaging that contains the **natural rubber**, and the outside package, container, or wrapper. Placement of cautionary statements in these locations should warn consumers adequately of the possible risks of allergic reactions to the packaging, while avoiding the potential for confusion that the actual products contain **natural rubber**.

FDA believes that requiring **devices** to remain in their original package at the user site, requiring labeling statements on dispensers that are sold separately from the **natural rubber containing devices**, and requiring user facilities to provide education concerning latex products and to monitor bulk product use, is impracticable and beyond the scope of the regulation. Furthermore, because of the potential manufacturing difficulties, the agency will not require **devices** to be embossed, imprinted, or otherwise labeled on the individual, unwrapped device. The agency believes that the labeling requirements in this regulation will provide adequate protection to the users and patients.

16. The vast majority of comments supported the removal of the ``hypoallergenic'' claim from the labeling of **medical devices** that contain **natural rubber**. Those comments that expressed unease about the removal of the claim stated that the term does convey meaningful information to the user. These comments suggested that an alternative term be applied, or that the regulation allow device labeling to state that the device presents a reduced potential for sensitizing users to **natural rubber**, or that the device contains less than a specified limit of **natural** latex proteins or processing chemicals as established by the agency. One comment stated that, until the agency proves that the tests currently employed are insufficient to support the ``hypoallergenic'' claim, the claim should be allowed.

The agency agrees that the term ``hypoallergenic'' provides important information to the consumer who is sensitive to processing chemicals, but believes that the term ``hypoallergenic'' on products **containing natural rubber** will mislead consumers to conclude erroneously that the product may not cause latex protein allergic reactions.

In the past, manufacturers have labeled their products ``hypoallergenic'' on the basis of results of the modified (human) Draize test. While this test may be appropriate for detecting sensitivity to residual levels of processing chemicals, the test cannot detect the presence of **natural** latex proteins. Furthermore, current manufacturing processes cannot reduce the levels of **natural** latex proteins below that to which some individuals may react.

The agency disagrees that the ``hypoallergenic'' label should be allowed to remain on **devices** that contain **natural rubber** until the agency proves that the tests currently employed are insufficient to support the ``hypoallergenic'' claim, or that claims should be allowed regarding reduced levels of latex proteins. The agency has received reports of allergic reactions to **natural rubber** gloves labeled as hypoallergenic. Given that the modified (human) Draize Test is not designed to detect levels of **natural** latex proteins that would not induce allergic responses, and that the agency is not aware of any current manufacturing processes that are designed to remove latex proteins below a level that may cause adverse reactions, the agency believes that it has sufficient evidence that the tests currently employed do not support the claim ``hypoallergenic'' with respect to the potential for allergic reactions to **natural** latex proteins.

The agency does agree that alternative statements should be applied to convey information about **devices** with reduced residual chemical levels to consumers who are sensitive to chemicals. For this reason,

the agency is developing guidance for manufacturers who want to make claims relating to latex **devices** that have reduced manufacturing chemical residues. FDA will announce the availability of this draft guidance document entitled ``Testing for Skin Sensitization to Chemicals in Latex Products'' in a future issue of the Federal Register.

17. A few comments stated that the reference to the draft guidance document entitled ``Testing for Skin Sensitization to Chemicals in Latex Products'' in the preamble to the June 24, 1996 proposed rule, upon which this final rule is based, was inappropriate because the document is still in draft form, while another comment suggested the agency reference the draft guidance document in the regulation itself.

The agency does not believe it is appropriate to incorporate a draft guidance document into a regulation. The agency, however, does believe that

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it is appropriate to use the preambles of a proposed and final rule relating to latex **devices** to inform the public that the agency is in the process of developing a guidance document relating to claims about the sensitizing potential of manufacturing chemical residues in latex **devices**.

18. The vast majority of comments supported the use of a symbol to indicate the presence of **natural rubber** in a device. These comments stated that the symbol would promote consumer recognition and could be used on **devices** that have labels that are too small to fit the full text of the statement. One comment suggested that the symbol be stamped on the actual **devices**, especially those sold in bulk packages. Some comments stated that the symbol should supplement, not replace the text

of the statement. Those comments not supporting the use of a **natural rubber** symbol cautioned that a symbol should not be used until it is universally accepted. Another comment suggested that the agency establish the symbol and require its use.

The agency agrees that a symbol would be useful. The agency stresses, however, that any symbol is intended to supplement, not replace the required written labeling statements, and its use would be voluntary. The agency appreciates the comments and the suggested symbol designs that were submitted, but does not believe that there is sufficient acceptance of a symbol to require the use of a symbol at this time.

19. Several comments stated that the health benefits of the labeling statement are potentially so great that the effective date of the requirement should be less than 180 days from the date of publication of this final rule. Other comments complained that a 180-day implementation period is not sufficient to change the labeling on the numerous **devices** affected by this rule. These comments requested at least a 12-month implementation period. One of these comments further requested that implementation be a two-stage process, and that **devices containing** dry **natural rubber** not be required to carry the labeling statement until 24 months after publication of this final rule. Another comment requested a two-stage implementation process so that **devices** that only indirectly contact humans would not be required to carry the labeling statement until 36 months after publication, or that such **devices** not be required to carry any labeling statement.

The agency agrees that the public health concerns relating to allergic responses to **natural rubber** are great. The agency also acknowledges, however, that at the time of the publication of this regulation, manufacturers have labeling in stock that does not have the required statements. In order to minimize the burden to manufacturers

of discarding labeling that has already been printed, and to allow sufficient time to reformat labeling, the agency is providing that the effective date of this final rule is 1 year after the date of publication. This effective date will allow most manufacturers sufficient time, before the effective date of this rule, to exhaust their existing supply of labeling stock. If a manufacturer uses the existing labeling stock before the effective date of this rule, however, FDA encourages manufacturers to add the required labeling statement at that time.

The agency does not believe that a two-stage implementation process is necessary, or that a period of longer than 1 year is necessary because 1 year should be adequate time to phase in new labeling, and reformat the labeling. Furthermore, the agency believes that a longer delay in the implementation of this rule would not be in the interest of the public health. The comment suggesting that **devices** that only indirectly contact humans not carry any **natural rubber** labeling statement is addressed in comment 4 of this document.

20. One comment suggested that manufacturers, distributors, and user facilities all be responsible for following the labeling requirements.

The agency agrees with the underlying concern that the labeling statement remain on **devices**. It is only necessary, however, to require manufacturers to properly label their products to ensure that consumers receive appropriate information concerning **natural rubber** products. Distributors and user facilities may not alter the device labeling. Any such alteration may be grounds for a charge of misbranding a device under sections 201(n) and 502(a), (c), and (f) of the act (21 U.S.C. 352(a), (c), and (f)).

21. A few comments complained that the rule could be misinterpreted to require labeling on all **devices containing** any **natural rubber**

whatsoever. Others stated that the requirement would have a major impact on multinational companies, costing at least $15,000 per device for labeling. Another comment stated that the agency underestimated the impact of the rule, as each manufacturer will need to draft, review, and relabel primary and secondary packages of hundreds, if not thousands of **devices**.

The agency has clarified the scope of this regulation in order to minimize the possibility of misinterpretation. Under final Sec. 801.437(b), an appropriate labeling statement is required on **medical devices** that contain **natural rubber** latex or dry **natural rubber** that contacts humans. The agency does not believe that this rule would require relabeling for hundreds or thousands of **devices**. In fact, the agency has only identified approximately 70 generic types of **medical devices** including combination products that are subject to this rule.

Furthermore, FDA does not agree that this rule will have a major impact on multinational companies because it would cost at least $15,000 per device for labeling. FDA estimates that the cost to revise the labeling would be between $1,000 and $2,000 for each type of device that is relabeled. Moreover, the cost of implementing this regulation is further minimized because the 1-year effective date of this regulation should allow most manufacturers to exhaust their current labeling stock prior to using the labeling that is required under this regulation.

IV. Paperwork Reduction Act of 1995

The warning statements required by this regulation are ``public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public * * *'' (5 CFR 1320.3(c)(2)). Accordingly, FDA concludes that the labeling

requirements in this final rule are not subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The

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agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under

the Executive Order.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This rule primarily requires a labeling change which would not have a significant economic impact on small entities. Although this rule will require a labeling change on a substantial number of **medical devices**, manufacturers will be allowed up to 1 year after the effective date of this regulation to exhaust their existing supply of labeling, therefore, most manufacturers would exhaust their existing supply of labels. Moreover, the cost of reformatting the labeling, which is $1,000 to $2,000 for each different kind of device, is not significant. Accordingly, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 801

Labeling, **Medical devices**, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 801 is amended as follows:

PART 801--LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

2. Section 801.437 is added to subpart H to read as follows:

Sec. 801.437 User labeling for **devices** that contain **natural rubber**.

(a) Data in the **Medical** Device Reporting System and the scientific literature indicate that some individuals are at risk of severe anaphylactic reactions to **natural** latex proteins. This labeling regulation is intended to minimize the risk to individuals sensitive to **natural** latex proteins and protect the public health.

(b) This section applies to all **devices** composed of or **containing**, or having packaging or components that are composed of, or contain, **natural rubber** that contacts humans. The term ``**natural**

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rubber'' includes **natural rubber** latex, dry **natural rubber**, and synthetic latex or synthetic **rubber** that contains **natural rubber** in its formulation.

(1) The term ``**natural rubber** latex'' means **rubber** that is produced by the **natural rubber** latex process that involves the use of **natural** latex in a concentrated colloidal suspension. Products are formed from **natural rubber** latex by dipping, extruding, or coating.

(2) The term ``dry **natural rubber**'' means **rubber** that is produced by the dry **natural rubber** process that involves the use of coagulated **natural** latex in the form of dried or milled sheets. Products are formed from dry **natural rubber** by compression molding, extrusion, or by converting the sheets into a solution for dipping.

(3) The term ``contacts humans'' means that the **natural rubber** contained in a device is intended to contact or is likely to contact the user or patient. This includes contact when the device that contains **natural rubber** is connected to the patient by a liquid path or an enclosed gas path; or the device **containing** the **natural rubber** is fully or partially coated with a powder, and such powder may carry **natural rubber** proteins that may contaminate the environment of the user or patient.

(c) **Devices containing natural rubber** shall be labeled as set forth in paragraphs (d) through (h) of this section. Each required labeling statement shall be prominently and legibly displayed in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(c)).

(d) **Devices containing natural rubber** latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

``Caution: This Product Contains **Natural Rubber** Latex Which May

Cause Allergic Reactions.''

This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

(e) **Devices containing** dry **natural rubber** that contacts humans, as described in paragraph (b) of this section, that are not already subject to paragraph (d) of this section, shall bear the following statement in bold print on the device labeling:

``This Product Contains Dry **Natural Rubber**.''

This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

(f) **Devices** that have packaging **containing natural rubber** latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

``Caution: The Packaging of This Product Contains **Natural Rubber** Latex Which May Cause Allergic Reactions.''

This statement shall appear on the packaging that contains the **natural rubber**, and the outside package, container, or wrapper.

(g) **Devices** that have packaging **containing** dry **natural rubber** that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

``The Packaging of This Product Contains Dry **Natural Rubber**.''

This statement shall appear on the packaging that contains the **natural rubber**, and the outside package, container, or wrapper.

(h) **Devices** that contain **natural rubber** that contacts humans, as described in paragraph (b) of this section, shall not contain the term

``hypoallergenic'' on their labeling.

(i) Any affected person may request an exemption or variance from the requirements of this section by submitting a citizen petition in accordance with Sec. 10.30 of this chapter.

(j) Any device subject to this section that is not labeled in accordance with paragraphs (d) through (h) of this section and that is initially introduced or initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under sections 201(n) and 502(a), (c), and (f) of the act (21 U.S.C. 321(n) and 352(a), (c), and (f)).

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William K. Hubbard,

Associate Commissioner for Policy Coordination.

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