

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

**TESTING FOR SENSITIZING CHEMICALS
IN NATURAL RUBBER LATEX MEDICAL DEVICES**

**List of groups/individuals capable of testing allergic
individuals:**

This partial list was compiled to assist manufacturers wishing to perform testing of their products on individuals sensitized to natural rubber latex chemical additives. It does not include all potential groups and individuals with the access to sensitized individuals, and is not a specific endorsement by FDA of individuals or groups listed. The American Contact Dermatitis Society has more than 300 members and a number of them may have clinical facilities to perform such testing.

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