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.

(MS 3/16/94)

DRAFT REVIEWER GUIDANCE ON FACE MASKS AND SHIELDS FOR CPR

All such devices may contain a one-way valve and must be labeled: "For emergency use only by persons properly trained in CPR and in the use of this device." Any claims relating to protection from diseases, e.g. AIDS, T.B. must be substantiated by the results of clinical trials.

If no part of the device extends into the patient's oral cavity by more than 2 cm, and there is no capability for using oxygen, then the device may be suitable for OTC distribution and may be classified under 21 CFR 868.8570 as a non-rebreathing valve, 73 CBP, Class II.

If any part of the device extends into the patient's oral cavity by more than 2 cm, then the device requires the prescription label: "Federal law restricts this device to sale by or on the order of a physician." If there is no capability for using oxygen, then the device may still be classified under 21 CPR 868.5870 as a non-rebreathing valve, 73 CBP, Class II.

If there is any capability for using oxygen, then the device requires the prescription label: "Federal law restricts this device to sale by or on the order of a physician." This device may be classified under 21 CFR 5570 as a non-rebreathing mask, 73 KGB, Class II.