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.

DCRND

REVIEW GUIDELINES FOR OXYGEN GENERATORS AND OXYGEN EQUIPMENT FOR EMERGENCY USE

Draft Document

draft

Office of Device Evaluation
Division of Cardiovascular, Respiratory and Neurological Devices
Anesthesiology, Defibrillators and Respiratory Devices Group

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

REVIEW GUIDELINES

FOR OXYGEN GENERATORS

AND

OXYGEN EQUIPMENT

FOR EMERGENCY USE

draft

Prepared by:

Anesthesiology, Defibrillators and
Respiratory Group
Division of Cardiovascular, Respiratory and
Neurological Devices
Office of Device Evaluation

REVIEW GUIDELINES FOR OXYGEN GENERATORS AND OXYGEN EQUIPMENT INTENDED FOR EMERGENCY USE

Oxygen generators and oxygen equipment intended for emergency use may be marketed for over-the-counter (OTC) distribution, provided such devices deliver a minimum flow rate of 6 liters of oxygen per minute, maintained for a minimum of 15 minutes. This flow rate establishes a minimum total oxygen delivery capacity of 90 liters for these devices. Labeling for the emergency use of oxygen generators and oxygen equipment for OTC use may not contain references to heart attacks, strokes, shock or any other medical condition which only licensed practitioners diagnose or treat.

Devices which do not meet the minimum flow rate criteria of 6 liters of oxygen per minute, maintained for 15 minutes, are regarded as prescription devices and must bear the prescription legend, provided that these devices have a minimum total oxygen delivery capacity of 90 liters. These devices are considered to have therapeutic value, but may not be labeled for emergency use.

Devices which are unable to provide a minimum total oxygen delivery capacity of 90 liters, regardless of minimum flow rate, will be considered not substantially equivalent to devices in commercial distribution.

draft