FDA is requesting emergency processing and OMB clearance for the Interim Final Rule (IFR): Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile (SNS). FDA is also requesting waiver of public comment under the emergency processing procedures on the information collection provisions related to the IFR. FDA is requesting these actions so the IFR will be effective immediately upon publication in the Federal Register. Delay of the effective date for the IFR to allow for comment on the information collection provisions would not allow regulatory procedures to be in place to respond to any requests for exceptions or alternatives under the IFR. Public comments would be requested upon publication of the IFR under the normal procedures used for rulemaking.

FDA is issuing this IFR to allow for exceptions or alternatives to specified labeling requirements for certain medical products that are or will be in the SNS. Compliance with these labeling requirements in some circumstances could adversely affect or compromise the safety, effectiveness or availability of these products. Exceptions or alternatives to certain labeling requirements will provide the flexibility needed to help ensure that FDA-regulated medical products that are or will be in the SNS are not deemed misbranded and are available in an emergency situation. Under the regulations provided in the IFR, the appropriate FDA Center Director may grant a request for an exception or alternative to certain regulatory provisions pertaining to the labeling of human drugs, biological products, and medical devices that currently are or will be included in the SNS if certain criteria are met.

An emergency requiring deployment of medical products in the SNS could happen at any time. Without this rule, the safety, effectiveness, or availability of medical products held in the SNS could be adversely affected because of relabeling requirements. The IFR ensures that a legal mechanism is immediately available for addressing labeling issues associated with medical products in the SNS without compromising their safety, effectiveness, or availability for use in an emergency. Products held in the SNS should be ready for deployment at all times, and a waiver of public comment on the information collection provisions would enable manufacturers and FDA to take immediate steps upon publication of the IFR to help ensure the safety, effectiveness, and availability of stockpiled medical products.