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.

SHELF LIFE OF MEDICAL DEVICES

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Geoffrey S. Clark
Microbiologist
Division of Small Manufacturers Assistance
Office of Training and Assistance
Center for Devices and Radiological Health
Food and Drug Administration

TABLE OF CONTENTS

NOTE: The excerpts of documents included throughout this paper have been edited.

INTRODUCTION

The potential benefit from the use of a medical device ranges from relieving minor irritations to correcting life threatening conditions. If the device design and manufacturing processes are done adequately, there is a high probability that the device will perform as desired at the time it is manufactured. However, there are many naturally occurring factors that can affect how long after manufacturing the device will maintain the ability to fully perform the intended function.

Shelf life is the term or period during which a commodity remains suitable for the intended use. An expiration date is the termination of shelf life, after which a percentage of the commodity, e.g., medical devices, may no longer function as intended. To determine if a particular device requires a shelf life and assign an expiration date, there are a number of different parameters that must be considered. The device must be analyzed to determine if it is susceptible to degradation that would lead to functional failure and the level of risk that the failure would present. For some devices, e.g., tongue depressors, it is not reasonable to assign a shelf life because of the small likelihood of time-dependant product degradation and the lack of serious consequences if it did fail to perform as designed. For certain devices susceptible to degradation that are intended to treat life-threatening conditions, e.g., pacemakers, the failure rate should approach zero within the labeled shelf life.

The purpose of this document is to:

- inform readers of the Food and Drug Administration (FDA) regulations and policies relating to shelf life of medical devices.
- discuss the various parameters that determine the length of time a particular device will remain within acceptable specifications;
- outline the different activities that can be undertaken to establish the shelf life of a device; and

STABILITY CRITERIA AND VARIABLES

The United States Pharmacopoeia (USP) defines stability as "*the extent to which a product retains, within specified limits, and throughout its period of storage and use, i.e., its shelf life, the same properties and characteristics that it possessed at the time of manufacture.*" There is no one exhaustive set of criteria that would apply equally to all medical devices. The USP has a section <1191> entitled "Stability Considerations in Dispensing Practice" that supplies general information on this topic. It includes a list of five sets of criteria for acceptable levels of stability for drug products as follows on the next page:

1. chemical,
2. physical,
3. microbiological,
4. therapeutic, and
5. toxicological.

Although this set of criteria applies specifically to the evaluation of drug product stability, it is useful as a starting point in developing a set of criteria to evaluate the stability of medical devices.

The following outline may be useful in identifying parameters that could significantly affect the shelf life of a device, even though all of the criteria will not apply to every device. This outline is based on the criteria listed above with the addition of biocompatibility.

1. Chemical

1.1 Degradation: Do any active ingredients or components of the device degrade over time in a manner which adversely affects device safety or performance?

1.2 Interactions: Do ingredients or components interact to alter the device? Does the device have interactions among the various components that cause degradation of the ability to perform the intended function?

1.3 Device and Packaging Interaction: Is there interaction between the device and package that has undesirable affects?

1.4 Radioactive Decay: Does the device contain radioactive material with a relatively short half-life? Do the radioactive decay by-products alter the safety or effectiveness of the device either by themselves or through further interaction?

1.5 Manufacturing: Do any of the manufacturing processes alter the chemistry of the raw materials, components, or finished device in a manner which adversely affects device safety or performance?

2. Physical

2.1 Physical Characteristics: Does the device have physical characteristics that vary with time; e.g., appearance, viscosity, elasticity, tensile strength, burst strength, or electrical resistance? In some cases, a significant change in appearance may cause concern to the user even though the performance of the device is not affected.

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