Guidance for Industry

OTC Treatment of Hypercholesterolemia

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I. INTRODUCTION

Recent interest expressed in marketing cholesterol-lowering agents as over-the-counter (OTC) drug products has raised several regulatory policy and medical therapy issues. Because of the interest in this subject on the part of individuals, professional groups, and drug manufacturers, the Center for Drug Evaluation and Research (CDER) has decided to state publicly its current view on this matter.

II. DISCUSSION

OTC drugs generally are used for self-recognizable conditions that are symptomatic, require treatment of short duration, and can be treated without the oversight and intervention of a health care practitioner.

Hypercholesterolemia, in contrast, is a chronic, unremitting, asymptomatic condition with life-threatening consequences that can be reduced by some interventions. Based on the available evidence reviewed at a May 13, 1997, meeting of an advisory committee involving the Non-Prescription Drugs Advisory Committee and the Endocrine and Metabolic Drugs Advisory Committee, the advisory committee concluded that the treatment of hypercholesterolemia requires both (a) accurate diagnosis and clinical testing and (b) careful health care practitioner-directed medical management, including the choice of appropriate drug(s) for the individual patient based on the patient's specific clinical condition. Because of this conclusion, the advisory committee recommended, in general, that drug treatments for hypercholesterolemia not be sold OTC in the United States.

At this time, CDER concurs with the conclusion of the advisory committee. It is CDER's view that (a) health care practitioner supervision in the diagnosis and ongoing management of hypercholesterolemia is essential for safe and effective use of drug products to treat this condition and (b) this supervision is assured within the context of prescription access to the appropriate drug(s) for the individual patient. CDER therefore believes that drugs for the treatment of hypercholesterolemia should not be sold OTC in the United States.

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[1]This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. This guidance represents the Agency's current thinking on the OTC treatment of hypercholesterolemia. It does not create or confer any 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 requirement of the applicable statute, regulations, or both.