

JUN 28 2000

CHOLESTECH 

 **WellCheck**

Warren E. Pinckert II
FDA OTC Part 15 Hearing
June 28, 2000

Technology Exists To Enable
Consumers To Effectively Use OTC
Medications to Improve Their
Personal Health

CHOLESTECH 

 **WellCheck**

00N-1256

TS 18¹

Technology

- Diagnostic -
Accurate risk assessment and therapy monitoring.
- National testing -
People convenient locations; professional counseling
- Tools for personal health management -
Interactive internet websites; direct mail.

CHOLESTECH 

 WellCheck

Diagnostic Technology

- Governed by CLIA.
- Portable, accurate, easy to use.
- Effective for mass risk assessment & therapy monitoring.
- Cholestech L·D·X®

CHOLESTECH 

 WellCheck

Waiver Under CLIA

- Precise and accurate stratified risk assessment.
- Risk assessment at location convenient to people.
- Convenient, cost effective monitoring of OTC products.
- Accurate and precise at medical decision points.

CHOLESTECH 

 **WellCheck**

National Testing

- Employers, retail locations, health & fitness centers.
- NIH guidelines testing; risk stratified.
- Professional, physician guided counseling.
- Risk assessment sent to primary care physician.
- Repeat testing for monitoring.
- Cost borne by “disease interested” partners.

CHOLESTECH 

 **WellCheck**

Internet Interactive Tools / Direct Mail

- Education on risk; professional risk assessment
- Professional goal setting in lifestyle, nutrition, fitness.
- Tracking against goals.
- Motivation to reach goals.

CHOLESTECH 

 WellCheck

The Tools Exist for Effective
Personal Health Management

CHOLESTECH 

 WellCheck