

DE LUCA ET AL - 25-HCC

Patent issued February 23, 1971

Upjohn Company licensed July 1, 1973

Development programs began 4th quarter 1973

Pre-NDA report on 25-OHD₃ in renal disease made to FDA
in 1976; additional data requested causing delay in
meeting until February 1978

NDA for 25-OHD₃ in renal disease filed with FDA on May 14, 1979
Calderol[®] approved for use in treatment of metabolic bone disease
in dialysis patients on August 5, 1980

Marketing began October 1980

Summary

Patent issued	February 1971		
Patent licensed	July 1973	- 2 years	5 months
NDA filed	May 1979	- 5 years	10 months
FDA approval	August 1980	- 1 year	3 months
Marketing began	October 1980	-	<u>2 months</u>
		9 years	8 months
Remaining Patent life		<u>7 years</u>	<u>4 months</u>
	Total	17 years	

DE LUCA ET AL - 25-HCC

Patent issued February 23, 1971
Upjohn Company licensed July 1, 1973
Development programs began 4th quarter 1973
Pre-NDA report on 25-OHD₃ in renal disease made to FDA
in 1976; additional data requested causing delay in
meeting until February 1978
NDA for 25-OHD₃ in renal disease filed with FDA on May 14, 1979
Calderol[®] approved for use in treatment of metabolic bone disease
in dialysis patients on August 5, 1980
Marketing began October 1980

Summary

Patent issued	February 1971		
Patent licensed	July 1973	- 2 years	5 months
NDA filed	May 1979	- 5 years	10 months
FDA approval	August 1980	- 1 year	3 months
Marketing began	October 1980	-	<u>2 months</u>
		9 years	8 months
Remaining Patent life		<u>7 years</u>	<u>4 months</u>
	Total	17 years	

DE LUCA ET AL - 25-HCC

Patent issued February 23, 1971

Upjohn Company licensed July 1, 1973

Development programs began 4th quarter 1973

Pre-NDA report on 25-OHD₃ in renal disease made to FDA
in 1976; additional data requested causing delay in
meeting until February 1978

NDA for 25-OHD₃ in renal disease filed with FDA on May 14, 1979
Calderol[®] approved for use in treatment of metabolic bone disease
in dialysis patients on August 5, 1980

Marketing began October 1980

Summary

Patent issued	February 1971		
Patent licensed	July 1973	- 2 years	5 months
NDA filed	May 1979	- 5 years	10 months
FDA approval	August 1980	- 1 year	3 months
Marketing began	October 1980	-	<u>2 months</u>
			9 years 8 months
Remaining Patent life			<u>7 years 4 months</u>
	Total	17 years	

DE LUCA ET AL - 25-HCC

Patent issued February 23, 1971

Upjohn Company licensed July 1, 1973

Development programs began 4th quarter 1973

Pre-NDA report on 25-OHD₃ in renal disease made to FDA
in 1976; additional data requested causing delay in
meeting until February 1978

NDA for 25-OHD₃ in renal disease filed with FDA on May 14, 1979
Calderol[®] approved for use in treatment of metabolic bone disease
in dialysis patients on August 5, 1980

Marketing began October 1980

Summary

Patent issued	February 1971		
Patent licensed	July 1973	- 2 years	5 months
NDA filed	May 1979	- 5 years	10 months
FDA approval	August 1980	- 1 year	3 months
Marketing began	October 1980	-	<u>2 months</u>
		9 years	8 months
Remaining Patent life		<u>7 years</u>	<u>4 months</u>
	Total	17 years	