



Department of State

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PAGE 01 BRASIL 03960 01 OF 02 120928Z
 ACTION STR-20

INFO	LOG-00	COPY-01	ADS-00	AID-00	INR-10	EUR-00	SS-00
OIC-02	AF-00	CIAE-00	EB-08	DINT-05	DODE-00	H-01	
IO-17	NEA-06	NSCE-00	ARA-00	NSAE-00	SSO-00	MED-07	
L-03	LOC-01	LAB-04	CTME-00	TRSE-00	EAP-00	ITC-01	
PA-01	CEA-01	OMB-01	SIL-01	HMS-04	INRE-00	FRB-03	
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 FM AMEMBASSY BRASILIA
 TO SECSTATE WASHDC IMMEDIATE 6501
 INFO USDOC WASHDC IMMEDIATE
 USMISSION GENEVA
 AMCONSUL RIO DE JANEIRO
 AMCONSUL SAO PAULO
 AMCONSUL PORTO ALEGRE POUCH
 AMCONSUL RECIFE POUCH
 AMCONSUL SALVADOR DA BAHIA POUCH

~~CONFIDENTIAL~~ SECTION 01 OF 02 BRASILIA 03960

PASS USTR FOR CHRISTINA LUND

GENEVA FOR USTR

USDOC FOR 4330/IEP/WH/OSA FOR PETER FIELD

E.O. 12356: DECL: OADR
 TAGS: ETRD, EIND, USTR, BR, US
 SUBJECT: PROPOSED CONSULTATIONS ON PHARMACEUTICALS

REF: A) STATE 102584
 - B) BRASILIA 2371
 - C) STATE 102165
 - D) BRASILIA 3291
 - E) BRASILIA 2979

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PAGE 02 BRASIL 03960 01 OF 02 120928Z

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1. ~~6~~ - ENTIRE TEXT.

2. SUMMARY. EMBASSY HAS DELIVERED DIPLOMATIC NOTE TO MINISTRY OF EXTERNAL RELATIONS (MRE) REQUESTING CONSULTATIONS AT "EARLIEST POSSIBLE OPPORTUNITY" WITH GOB "...REGARDING THE IMPACT OF RELEVANT BRAZILIAN LAWS, DECREES, REGULATIONS, POLICIES AND PRACTICES AS THEY AFFECT UNITED STATES TRADE AND INVESTMENT IN THE PHARMACEUTICAL AND FINE CHEMICAL AREAS." MRE ECONOMIC DEPARTMENT CHIEF, AMBASSADOR SEBASTIAO REGO BARROS NETO, SPEAKING ON A PERSONAL BASIS, TOLD ECONOMIC COUNSELOR THAT HE THOUGHT IT WOULD BE POSSIBLE TO ACCOMMODATE THE USG REQUEST. END SUMMARY.

3. AS INSTRUCTED REF (A), ECONOMIC COUNSELOR ON APRIL 10 DELIVERED DIPLOMATIC NOTE REQUESTING BILATERAL CONSULTATIONS ON PHARMACEUTICALS AND FINE CHEMICALS "AT THE EARLIEST POSSIBLE OPPORTUNITY" TO MRE ECONOMIC DEPARTMENT CHIEF AMBASSADOR REGO BARROS. SUBSTANTIVE TEXT OF NOTE NO. 123 OF APRIL 9, 1986 IS AS FOLLOWS:

BEGIN SUBSTANTIVE TEXT.

"...AND HAS THE HONOR TO REQUEST BILATERAL CONSULTATIONS IN BRASILIA AT THE EARLIEST POSSIBLE OPPORTUNITY WITH THE APPROPRIATE BRAZILIAN AUTHORITIES REGARDING THE IMPACT OF RELEVANT BRAZILIAN LAWS, DECREES, REGULATIONS, POLICIES AND PRACTICES AS THEY AFFECT UNITED STATES TRADE AND INVESTMENT IN THE PHARMACEUTICAL AND FINE CHEMICAL

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PAGE 03 BRASIL 03960 01 OF 02 120928Z

AREAS.

"THE AREAS OF CONCERN TO THE UNITED STATES GOVERNMENT, AND WHICH THE EMBASSY OF THE UNITED STATES OF AMERICA WISHES TO DISCUSS AT THE PROPOSED CONSULTATIONS, INCLUDE:

- -- THE LACK OF ADEQUATE PATENT PROTECTION;
- -- REGULATION OF FOREIGN INVESTMENT;

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- -- PRICING POLICIES AND PRICE CONTROLS; AND
- -- REGISTRATION OF NEW PRODUCTS
- "THE UNITED STATES GOVERNMENT LOOKS FORWARD TO RECEIVING THE GOVERNMENT OF BRAZIL'S RESPONSE TO THIS REQUEST FOR CONSULTATIONS."
END SUBSTANTIVE TEXT.
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- 4. PRESENTATION OF DIPLOMATIC NOTE WAS FOLLOW-UP TO APRIL 8 CONVERSATION BETWEEN AMB. REGO BARROS AND ECONOMIC COUNSELOR. ECONOMIC COUNSELOR EXPLAINED REASONS FOR USG CONCERNS, DRAWING ON MATERIAL IN REFS (A) AND (C). NOTING THAT GOB OFFICIALS HAD PROTESTED, WHEN USG INITIATED SECTION 301 INFORMATICS CASE, THAT THE APPROPRIATE PROCEDURES WOULD HAVE BEEN TO SEEK BILATERAL CONSULTATIONS, ECONOMIC COUNSELOR SAID USG WELCOMES OPPORTUNITY TO TEST PROCESS SUGGESTED BY GOB IN DEALING WITH A BILATERAL TRADE PROBLEM OF MAJOR CONCERN TO USG. AMB. REGO BARROS, SPEAKING ON PERSONAL BASIS, REPLIED THAT HE THOUGHT GOB COULD ACCOMMODATE USG REQUEST. ECONOMIC COUNSELOR EMPHASIZED NEED TO BEGIN CONSULTATIONS ASAP.

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PAGE 04

BRASIL 03960 01 OF 02 120928Z

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PAGE 01 BRASIL 03960 02 OF 02 120930Z
 ACTION STR-20

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*FM AMEMBASSY BRASILIA
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~~CONFIDENTIAL~~ SECTION 02 OF 02 BRASILIA 03960

PASS USTR FOR CHRISTINA LUND

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E.O. 12356: DECL: OADR

TAGS: ETRD, EIND, USTR, BR, US

SUBJECT: PROPOSED CONSULTATIONS ON PHARMACEUTICALS

*5. TO ACHIEVE MAXIMUM RESULTS FROM CONSULTATIONS,
 EMBASSY REQUESTS ASSISTANCE FROM WASHINGTON AGENCIES
 IN FOLLOWING AREAS:*

A. IT WOULD DIFFUSE GOB SENSITIVITIES IF WE COULD

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PAGE 02 BRASIL 03960 02 OF 02 120930Z

LET GOB KNOW THAT USG IS NOT SINGLING OUT BRAZIL ON
 PHARMACEUTICALS/FINE CHEMICALS. WE THEREFORE WOULD

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LIKE WASHINGTON'S PERMISSION TO INFORM GOB, DURING THE CONSULTATIONS, THAT SIMILAR REQUESTS FOR CONSULTATIONS ARE BEING/WILL BE PURSUED IN OTHER LATIN AMERICAN COUNTRIES.

B. TO DATE, OUR EFFORTS TO DEVELOP INFORMATION ON PHARMACEUTICALS/FINE CHEMICALS HAVE FOCUSED ON PRICING PRACTICES, NEW PRODUCT REGISTRATION, AND POTENTIAL MARKET RESERVE THREATS (REF B). WE ARE NOW TRYING TO DEVELOP DOCUMENTATION ON DAMAGE CAUSED BY LACK OF ADEQUATE PATENT PROTECTION. TO ASSIST IN OUR EFFORTS, WE WOULD APPRECIATE RECEIVING PMA STUDIES ON PIRACY MENTIONED IN REF (C), PARTICULARLY THOSE CASES NOTED IN PART II PARA (F). WE WOULD ALSO APPRECIATE ANY FURTHER DOCUMENTATION OF DAMAGES TO US FIRMS WHICH PMA CAN PROVIDE.

C. WE WOULD ALSO APPRECIATE WASHINGTON AGENCIES REACTION TO EMBASSY SUGGESTION TO SEEK EXPANDED BILATERAL COOPERATION BETWEEN FDA AND DIMED/MINISTRY OF HEALTH IN ORDER TO FACILITATE THE REGISTRATION OF NEW PRODUCTS IN BRAZIL (REF D). IT WOULD ALSO BE USEFUL FOR US TO KNOW, AS A POSSIBLE REBUTTAL POINT, THE AVERAGE TIME BETWEEN FILING FOR AND ISSUE OF A PATENT IN THE UNITED STATES.

6. FYI. ON THE OPERATION OF PORTARIA IV, A SENIOR COUNCIL FOR INDUSTRIAL DEVELOPMENT OFFICIAL (CDI) TOLD THE ECONOMIC COUNSELOR APRIL 7 THAT, SINCE THE INCEPTION OF PORTARIA IV, 8 MNC INVESTMENT

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PAGE 03 BRASIL 03960 02 OF 02 120930Z

PROJECTS AND 6 NCC PROJECTS HAD BEEN APPROVED. OF THE TWO MNC PROJECTS TURNED DOWN, THE RHODIA SALICYLIC ACID PROJECT, ACCORDING TO THIS OFFICIAL, IS BEING RECONSIDERED AND IS LIKELY TO BE RESOLVED SATISFACTORILY BY MAY. THE CORN PRODUCT SORBITOL INVESTMENT TURN-DOWN WAS BASED, ACCORDING TO THIS OFFICIAL, ON THE GROUNDS THAT NOT ONLY WAS THE DOMESTIC MARKET "FULLY SUPPLIED," BUT THAT THE CURRENT PRODUCER EXPORTED 40 PCT OF HIS PRODUCTION. ASKED WHAT THE INVESTMENT CRITERIA WAS FOR THE PHARMACEUTICAL/FINE CHEMICAL SECTOR, THIS OFFICIAL REPLIED THAT FOREIGN

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INVESTMENT WAS WELCOME TO SUBSTITUTE IMPORTS BUT NOT TO DISPLACE NATIONAL PRODUCTION IN A SECTOR ALREADY DOMINATED BY MNC'S. THE ECON COUNSELOR NOTED THAT PORTARIA IV DID NOT ESTABLISH ANY TIME LIMITS FOR CDI CONSIDERATION OF AN INVESTMENT PROPOSAL. THE CDI OFFICIAL AGREED AND CLAIMED THAT THEY DID NOT HAVE ENOUGH STAFF TO GUARANTEE THAT AN INVESTMENT WOULD BE CONSIDERED IN A LEGALLY MANDATED TIME PERIOD. HE DID CLAIM THAT MOST INVESTMENT PROPOSALS ARE CONSIDERED WITHIN A 60-90 DAY TIME FRAME. THIS OFFICIAL ALSO REVEALED THAT A NCC INVESTMENT PROPOSAL HAD BEEN TURNED DOWN BY CDI UNDER PORTARIA IV ON THE GROUNDS THAT THE PROPOSED PRODUCT WAS "MUCH WORSE" THAN SIMILAR PRODUCTS ALREADY ON THE MARKET. END FYI.
WATSON

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