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ACTION EB-08

INFO	LOG-00	COPY-01	ADS-00	AID-00	INR-10	SS-00	CIAE-00
	DINT-05	DODE-00	H-01	ARA-00	NSAE-00	SSO-00	L-03
	STRE-00	LAB-04	CTME-00	TRSE-00	ITC-01	PA-01	CEA-01
	OMB-01	STR-17	HHS-04	INRE-00	AGRE-00	FRB-03	OES-09
	USIE-00	JUSE-00	SP-02	PRS-01	E-01	/073 W	

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FM AMEMBASSY BRASILIA  
TO SECSTATE WASHDC IMMEDIATE 4544  
INFO USDOC WASHDC IMMEDIATE  
AMCONSUL RIO DE JANEIRO  
AMCONSUL SAO PAULO

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PASS USTR FOR AMBASSADOR SMITH

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

E.O.12356: DECL: OADR  
TAGS: EINV, ETRD, BR, US  
SUBJECT: RECENT PHARMACEUTICAL DEVELOPMENTS

REF(S): (A) SAO PAULO 00294  
- (B) SAO PAULO 00952

1. ~~CONFIDENTIAL~~ - ENTIRE TEXT

2. SUMMARY: RECENT DEVELOPMENTS IN THE PHARMACEUTICAL SECTOR PROVIDE A CLEAR INDICATION THAT THE GOB WANTS TO AVOID SECTION 301 ACTION ON PHARMACEUTICALS. WE HAVE MADE PROGRESS IN THREE OF THE FOUR AREAS RAISED AT LAST NOVEMBER'S BILATERAL CONSULTATIONS. THE GOB MIGHT AGREE TO FURTHER BILATERAL DISCUSSIONS ON THE PATENT PROTECTION ISSUE. IF THE GOB ACCEPTS FURTHER

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DISCUSSIONS ON THE PATENT PROTECTION ISSUE, WE BELIEVE THE PMA WOULD BE WELL ADVISED TO WITHHOLD A SECTION 301

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UNITED STATES DEPARTMENT OF STATE  
REVIEW AUTHORITY: NORMAN M. BOUTON  
DATE/CASE ID: 19 DEC 2001 200000143  
CLASSIFICATION: CONFIDENTIAL REASON: 1.6(6)  
DECLASSIFY AFTER: 15 APR 2012

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FILING. END SUMMARY.

3. OVER THE PAST FEW MONTHS, THE GOB HAS MOVED TO ADDRESS U.S. CONCERNS ON NEW PRODUCT REGISTRATIONS, PRICING AND CREEPING MARKET RESERVE (PORTARIA IV) IN THE PHARMACEUTICAL SECTOR.

4. AS A FIRST STEP TOWARD ADDRESSING THE NEAR TWO-YEAR PARALYSIS IN NEW DRUG PRODUCT REGISTRATIONS, PRESIDENT SARNEY ESTABLISHED JANUARY 14 THE NATIONAL HEALTH COUNCIL (CSN) WHICH SHIFTS NEW DRUG LICENSING AUTHORITY AWAY FROM DIMED (REF A). IN EARLY APRIL, MINISTER OF HEALTH ROBERTO SANTOS DISMISSED DIMED DIRECTOR SUELI ROSENFELD AND MEDICAL HEALTH STANDARDS CHIEF LUIS FELIPE MOREIRA LIMA, THE TWO KEY ACTORS RESPONSIBLE FOR THE REGISTRATION PARALYSIS.

5. ON THE CHRONIC PROBLEM OF INADEQUATE PRICE INCREASES, THE GOB HAS GRANTED SEVERAL PRICE INCREASES IN RECENT MONTHS (REF B), WHICH FOR THE FIRST TIME IN FIVE YEARS GIVES THE PHARMACEUTICAL INDUSTRY PRICE INCREASES THAT AT LEAST MATCH THE INFLATION RATE. THE GOB IS REPORTEDLY NEGOTIATING WITH THE PHARMACEUTICAL INDUSTRY A NEW AND MORE TRANSPARENT PRICING POLICY WHICH WOULD PROVIDE AN AUTOMATIC TRIGGER WHEN A COMPANY'S INFLATIONARY COSTS REACH 20 PERCENT. UNDER THIS NEW PRICING ENVIRONMENT, MOST COMPANIES ARE MAKING PROFITS.

6. ON THE ISSUE OF CREEPING MARKET RESERVE (PORTARIA IV), WE HAVE NOT RECEIVED ANY RECENT REPORTS THAT U.S. PHARMACEUTICAL FIRMS ARE EXPERIENCING DIFFICULTIES WITH

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THE COUNCIL OF INDUSTRIAL DEVELOPMENT (CDI).

7. WE BELIEVE THAT IF THE GOB WOULD AGREE TO CONTINUE SUBSTANTIVE DISCUSSIONS ON THE PATENT ISSUE, COUPLED WITH CONTINUED PROGRESS ON OTHER OPERATIONAL ISSUES, THE PMA WOULD BE WELL-ADVISED TO WITHHOLD FILING OF A 301 PETITION. SOME LOCAL U.S. PHARMACEUTICAL EXECUTIVES WORRY THAT THE GOB GOODWILL TO MAKE FURTHER PROGRESS ON THESE OPERATIONAL AREAS COULD BE LOST OVERNIGHT WITH A NASTY 301 CONFRONTATION.

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8. DURING AN APRIL 15 MEETING ON ANOTHER SUBJECT WITH ECONOMIC COUNSELOR AND ECON SECTION CHIEF, MINISTRY OF EXTERNAL RELATIONS

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[REDACTED] INDICATED THAT THE GOB IS CONSIDERING ANOTHER ROUND OF CONSULTATIONS ON PHARMACEUTICALS, AT WHICH THE PATENT PROTECTION ISSUE, AS WELL AS OTHER ISSUES, WOULD BE DISCUSSED. [REDACTED] SAID HE HOPED TO BE ABLE TO TABLE SUCH A SUGGESTION SOME TIME NEXT WEEK, AFTER COMPLETING INTRA-GOB CONSULTATIONS. [REDACTED] REFERRED TO RECENT GOB ACTIONS ON PRICING POLICY AND TO CHANGES IN THE SENIOR GOB BUREAUCRACY WHICH SUPERVISES THE PHARMACEUTICAL INDUSTRY AS HOPEFUL SIGNS. HE SAID THAT HE FEARED A SECTION 301 ACTION IN PHARMACEUTICALS WOULD NOT ONLY BLOCK FURTHER PROGRESS IN THE PHARMACEUTICALS AREA, BUT MIGHT ADVERSELY AFFECT THE OVERALL ATMOSPHERE FOR U.S.-BRAZIL TRADE RELATIONS.

9. THE GOB POSITION AGAINST PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS APPEARS TO BE BASED ON THE FEAR THAT PATENT PROTECTION WILL FREEZE THE MNC'S DOMINANT

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MARKET SHARE AND ON A REALIZATION THAT, AT PRESENT,  
MOST BRAZILIAN FIRMS SURVIVE BY PRODUCING COPYCAT  
DRUGS. WE BELIEVE THAT TO HAVE ANY REAL CHANCE OF  
CHANGING THE GOB POSITION ON PATENT PROTECTION, THERE  
WOULD HAVE TO BE SOME ARRANGEMENT WHEREBY THE NATIONAL  
PHARMACEUTICAL INDUSTRY WOULD SURVIVE AFTER ADOPTION OF  
PATENT PROTECTION.  
SHLAUDEMAN

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