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ACTION EB-08

INFO LOG-00 COPY-01 ADS-00 ARA-00 STR-20 INM-07 HHS-06
OES-09 SLPD-01 /052 W
----------075437 281014Z /23

R 261932Z MAR 86
FM AMEMBASSY BRASILIA
TO SECSTATE WASHDC 6121
INFO USDOC WASHDC
AMCONSUL RIO DE JANEIRO
AMCONSUL SAO PAULO
AMCONSUL PORTO ALEGRE POUCH
AMCONSUL RECIFE POUCH
AMCONSUL SALVADOR DA BAHIA POUCH

UNCLAS SECTION 01 OF 02 BRASILIA 03291

PASS USDOC FOR 4330/IEP/WH/OSA/PETER FIELD AND
4300/IEP/WH/DAS/ANN HUGHES

E.O. 12356: N/A
TAGS: EIND, BR, US
SUBJECT: COOPERATION ON DRUG REGISTRATION: REQUEST FOR
WASHINGTON VIEWS

REF: BRASILIA 2371

1. SUMMARY. REFTEL INTER ALIA DESCRIBED PROBLEMS ASSOCIATED WITH THE REGISTRATION OF NEW DRUG PRODUCTS IN BRAZIL AND SUGGESTED CONSIDERATION OF A BILATERAL UNDERSTANDING THAT WOULD FACILITATE REGISTRATION OF DRUGS ALREADY APPROVED BY U.S. AUTHORITIES. EMBASSY BELIEVES SUCH COOPERATION, IF POSSIBLE, WOULD HELP EASE PROBLEMS FACED BY U.S. PHARMACEUTICAL COMPANIES IN BRAZIL AND WOULD ALSO HELP BRAZILIANS OBTAIN ACCESS TO NEW PRODUCTS. IF WASHINGTON AGENCIES CONCUR, THE EMBASSY IS WILLING TO EXPLORE THIS WITH GOB OFFICIALS. UNCLASSIFIED

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WE WOULD APPRECIATE GUIDANCE ASAP ON THIS, AND IF FEASIBLE, IDEAS ON POSSIBLE FORMS OF COOPERATION. END

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SUMMARY.

2. AS WE UNDERSTAND IT, THE BRAZILIAN DRUG LICENSING PROCESS PROCESS IS IN TROUBLE: ONLY A FEW NEW-TO-MARKET DRUGS WERE REGISTERED IN 1985 AND ONLY ABOUT 40 PERCENT OF THE ESTIMATED 12,000 OR SO REQUESTS TO REGISTER RELATIVELY MINOR REFORMULATIONS WERE APPROVED. THIS WAS CONFIRMED DURING A RECENT DISCUSSION (SEE REFTEL PARA ((B)) WITH [redacted] OF THE NATIONAL SECRETARIAT OF HEALTH PROTECTION [redacted] WHO B6
DESCRIBED STAFFING AND OTHER TECHNICAL PROBLEMS THAT SHARPLY LIMITED HIS AGENCIES ABILITY TO ANALYZE NEW DRUG APPROVAL REQUESTS. (NOTE. THE APPROVAL PROCESS BEGINS WITH A COMPANY'S APPLICATION TO THE DEPARTAMENTO DE MEDICAMENTOS (DIMED), WHICH STUDIES THE APPLICATION AND DOCUMENTATION, PERFORMS ADDITIONAL TECHNICAL STUDIES AND ANALYSIS AS REQUIRED AND FORMULATES A RECOMMENDATION TO [redacted] NATIONAL SECRETARIAT OF HEALTH PROTECTION. THE NATIONAL SECRETARIAT ANALYZES THE DIMED REPORT, PERFORMS ANY ADDITIONAL ANALYSIS SEEMINGLY REQUIRED, AND EITHER ISSUES OR DENIES A LICENSE FOR SALE IN BRAZIL. THE NATIONAL HEALTH SECRETARIAT ALSO APPROVES AGRICULTURAL CHEMICALS, FOOD, COSMETICS, AND PESTICIDES, BASED ON THE WORK OF OTHER DIVISIONS. THESE ARE CONSIDERED LESS SENSITIVE. END NOTE) [redacted] B6
SAID THAT HE HAD BEEN IMPRESSED BY THE FDA'S TECHNICAL CAPABILITY AND INTEGRITY, DURING A VISIT, AND NOTED THAT HE HAD BEEN IN CONTACT WITH FDA ABOUT APPROVALS OF SOME SPECIFIC DRUGS.

4. [redacted] PROBLEMS MAY PROVIDE AN OPENING FOR
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EXPANDING BILATERAL COOPERATION IN THE PHARMACEUTICAL AREA. TO THE EMBASSY, IT WOULD SEEM TO BE IN THE INTEREST OF BOTH COUNTRIES TO WORK OUT SOME KIND OF ARRANGEMENT THAT WOULD PERMIT THE RESULTS OBTAINED FROM THE RESEARCH AND CLINICAL TESTING PROGRAM OF BOTH COUNTRIES TO SPEED THE REGISTRATION OF NEW DRUGS IN BOTH COUNTRIES. THAT AN ARRANGEMENT WOULD BENEFIT PHARMACEUTICAL PRODUCERS WAS CONFIRMED BY EMBASSY OFFICERS DURING INFORMAL DISCUSSIONS WITH [redacted]

[redacted] DURING AN INFORMAL CONVERSATION IN BRASILIA ON MARCH 22. AN AGREEMENT COULD POSSIBLY BE BASED ON THE FOLLOWING ELEMENTS:

(A) AN AGREEMENT BY BRAZIL TO ACCEPT REGISTRATION BY THE FDA AS THE EQUIVALENT OF THE BRAZILIAN REVIEW AND LICENSING PROCESS.

(B) AN UNDERSTANDING BY U.S. AUTHORITIES TO CONSIDER, AT SUCH A TIME THAT THE REGISTRATION AND LICENSING PROCESS IN BRAZIL IS CONSIDERED AT LEAST COMPARABLE TO THAT IN THE U.S., ACCEPTING BRAZILIAN GOVERNMENT REGISTRATION OF DRUGS AS EQUIVALENT TO OUR OWN. (COMMENT. THIS COULD BE A SENSITIVE AREA IN BOTH COUNTRIES. ON THE BASIS OF [redacted] COMMENTS ABOUT THE TECHNICAL CAPABILITY OF HIS STAFF, WE COULD NOT SUGGEST THAT FDA AGREE TO ACCEPT THE RESULTS OF THE BRAZILIAN LICENSING PROCESS AT THE PRESENT TIME. A POSSIBLE WAY OUT, AS SUGGESTED BY [redacted] COULD BE ACCEPTANCE BASED ON PRIOR FDA APPROVAL OF THE RESEARCH

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AND CLINICAL TESTING PROTOCOLS, AND REVIEW OF THE FINAL
RESULTS. END COMMENT)

(C) TECHNICAL EXCHANGE, EVENTUALLY PERHAPS OF
PERSONNEL, BETWEEN THE NATIONAL SECRETARIAT AND FDA ON
DRUG TESTING, RESEARCH PROTOCOLS, AND DRUG REGISTRATION,
DESIGNED PRIMARILY TO HELP IMPROVE THE QUALITITY AND
TIMELINESS OF THE DRUG REGISTRATION PROCESS IN BRAZIL.
SUCH A TECHNICAL PROGRAM COULD ALSO BE APPLIED AT THE
DIMED LEVEL, IF FEASIBLE.

6. THE EMBASSY DOES NOT KNOW ENOUGH ABOUT THE PROCESS
IN THE U.S. TO KNOW WHETHER THE ABOVE MAKE TECHNICAL OR
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ADMINISTRATIVE SENSE. NOR DO WE KNOW HOW THE GOB WOULD
RESPOND TO SUCH POSSIBLE PROPOSALS, IN VIEW OF
XENOPHOBIA THAT SEEMS TO PERVADE MUCH OF THE NATIONAL
HEALTH SECTOR HERE. AT LEAST INITIALLY, WE WOULD EXPECT
THIS TO BE OF GREATER DIRECT BENEFIT TO BRAZIL; WE WOULD
NOT EXPECT MANY REQUESTS TO REGISTER PRODUCTS IN THE
U.S. ON THE BASIS OF RESEARCH AND TESTS PERFORMED IN
BRAZIL. HOWEVER, WE DO STRONGLY BELIEVE THAT A USG
INITIATIVE TO PROVIDE ASSISTANCE TO BRAZILIAN
PHARMACEUTICAL AUTHORITIES MAKES A GREAT DEAL OF SENSE,
ECONOMICALLY AND POLITICALLY. WHILE GENUINELY

NEW-TO-MARKET DRUGS MAY BE FEW, THE BENEFITS OF ACCELERATING THE REGISTRATION PROCESS WOULD SEEM TO PAY LARGE BENEFITS FOR BOTH FOREIGN COMPANIES (LOGICALLY EXPECTED TO HAVE THE BULK OF THE NEW PRODUCTS) AND BRAZIL. REDUCING THE LEAD TIME OF COURSE GIVES THE INTRODUCING COMPANY A HEAD START ON THE COMPANIES THAT WOULD PIRATE THE NEW PRODUCT. IT WOULD ALSO BE HIGHLY COST EFFECTIVE FOR BRAZIL, BECAUSE NEW-TO-MARKET DRUGS TYPICALLY PROVIDE THE GREATEST IMPROVEMENTS OVER EXISTING DRUGS AND TREATMENTS.

6. THE EMBASSY ALSO BELIEVES THAT USG OBJECTIVES WOULD BE WELL SERVED BY A BILATERAL UNDERSTANDING. IT COULD INCREASE COOPERATION IN AN AREA WHERE AT THIS POINT WE SEEM TO BE HEADED ON A COLLISION COURSE. TECHNICAL COOPERATION, AND REGULAR EXCHANGES OF VIEWS BETWEEN LICENSING AUTHORITIES WOULD PROVIDE AN OPPORTUNITY FOR US TO PROMOTE PATENT PROTECTION FOR PHARMACEUTICALS, A KEY USG AND INDUSTRY OBJECTIVE.

7. ACTION REQUESTED. THE EMBASSY REQUESTS WASHINGTON CONSIDERATION OF THE PROPOSAL SET OUT ABOVE, GUIDANCE ON
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THE SCOPE AND SUBSTANCE OF POSSIBLE COOPERATION AND COMMENTS IF ANY ON HANDLING THE ISSUE WITH THE GOB, WITH WHOM THIS POSSIBILITY HAS NOT BEEN DISCUSSED.
WATSON