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PASS TO: USDOC FOR 4330/IEP/WH/OSA/PETER FIELD

USTR FOR AMBASSADOR SMITH AND JON ROSENBAUM

E.O.12356: DECL:OADR

TAGS: ETRD, EINV, BR, US

SUBJECT: PHARMACEUTICALS: THOUGHTS ABOUT THE JUNE

8 CONSULTATIONS

- 1. CONFIDENTIAL ENTIRE TEXT.
- 2. SUMMARY. THE UPCOMING CONSULTATIONS COULD DEVELOP INTO AN UNPRODUCTIVE BILATERAL CONFRONTATION THAT WOULD, INTER ALIA, RISK RECENT GAINS ON THE PROFITABILITY AND REGISTRATION ISSUES. WE MIGHT HELP AVOID SUCH AN OUTCOME BY FINDING A WAY TO INVOLVE DIRECTLY THE PMA, GIVING THEM AND THE GOB AN INCENTIVE TO MAINTAIN A POSITIVE DIALOGUE ON THE PATENT PROTECTION QUESTION. END SUMMARY

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3. A DANGER EXISTS THAT THE JUNE 8 CONSULTATIONS WILL NOT MOVE OUR DISCUSSION ON THE PATENT PROTECTION ISSUE.

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UNITED STATES DEPARTMENT OF STATE REVIEW AUTHORITY: NORMAN M. BOUTON DATE/CASE ID: 19 DEC 2001 200000143

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BEYOND THE DISAPPOINTING IMPASSE OF THE MARCH 16 TALKS. THERE IS NO BRAZILIAN POLITICAL CONSENSUS FOR PATENT PROTECTION ON PHARMACEUTICALS AND THE GOB IS NOT STRONG ENOUGH AT PRESENT TO PUSH PATENT PROTECTION LEGISLATION THROUGH, EVEN IF IT WERE CONVINCED OF THE NEED TO DO SO. THUS, MOVEMENT ON THIS ISSUE WILL DEPEND ON THE CREATION OF THE NECESSARY POLITICAL UNDERSTANDING. NO CHANGE IN THE BRAZILIAN PATENT LAW TO PROTECT PHARMACEUTICAL PRODUCTS WILL OCCUR, EVEN UNDER THE MOST PROMISING SCENARIO, UNTIL AFTER THE CONSTITUENT ASSEMBLY CLOSES.

IF WE ARE TO RESOLVE THE PATENT ISSUE WITHIN A REASONABLE PERIOD, WE WILL NEED THE PMA'S COOPERATION IN WORKING WITH THE GOB TOWARD A POSITIVE SOLUTION. IT SEEMS TO US THAT THE BEST WAY TO PROMOTE THIS COOPERATION AND UNDERSTANDING IS TO INCLUDE DIRECTLY THE PMA IN THE PROCESS, IN AN ADVISORY ROLE IN THE JUNE 8 CONSULTATIONS AND IN ANY SUBSEQUENT DIALOGUE. INDUSTRY REPRESENTATIVES PLAYED A VALUABLE ROLE IN THE PREVIOUS CONSULTATIONS; WE BELIEVE THEIR PRESENCE WOULD BE USEFUL IN THESE CONSULTATIONS AS WELL. THAT DURING THE FEBRUARY 5, 1987 MOTION PICTURE/VIDEOCASSETTE CONSULTATIONS, THE GOB ACCEPTED THE MOTION PICTURE EXPORT ASSOCIATION OF AMERICA (MPEAA) IN SUCH AN ADVISORY ROLE AND THE DECISION HAD A VERY POSITIVE IMPACT ON THE TALKS. NOT ONLY DID THE MPEAA REPS ADD A DIMENSION TO THE CONSULTATIONS THAT CANNOT BE FULLY CONVEYED BY BRIEFING PAPERS, BUT THE FACE-TO-FACE EXCHANGES ENABLED THE MPEAA TO UNDERSTAND THE POLITICAL CONSTRAINTS FACED BY GOB POLICY MAKERS.)

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5. IF A BREAK DOWN CAN BE AVERTED AT THE JUNE 8
CONSULTATIONS, WE WILL NEED TO CONSIDER HOW TO ENGAGE
CONSTRUCTIVELY AFTERWARDS. WE SUGGEST THE U.S.
DELEGATION AT THE JUNE 8 CONSULTATIONS URGE THE GOB TO
UNDERTAKE A REVIEW, DRAWING ON MATERIALS AND
SUGGESTIONS FROM THE PMA AND PRIVATE BRAZILIAN
INDUSTRY, THAT WOULD ANALYZE THE COSTS/BENEFITS OF
BRAZIL'S ADOPTING PATENT PROTECTION. A FAVORABLE STUDY
GROUP REPORT WOULD HELP THE GOB SELL A CHANGE IN
BRAZIL'S PATENT LAW AND DESTROY FEARS THAT THE ADOPTION

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OF PATENTS WILL LEAD TO A DESTRUCTION OF BRAZIL'S NATIONAL PHARMACEUTICAL INDUSTRY AND RAISE DRUG PRICES EXCESSIVELY. THIS REVIEW MIGHT ALSO EXAMINE VARIOUS ASPECTS OF THE PMA'S SHORT-TERM PROPOSALS. FOR INSTANCE, HOW WOULD "PIRATED" DRUGS BE IDENTIFIED AND DENIED REGISTRATION?

6. ADDITIONALLY, AT THE JUNE 8 CONSULTATIONS THE U.S. SHOULD INSIST THAT THE GOB CONSOLIDATE RECENT GAINS INTO A TRANSPARENT AND OBJECTIVE REGISTRATION AND PRICING SYSTEM. RECENT PRICE INCREASES ARE BEING RAPIDLY ERODED BY 20 PERCENT PLUS PER MONTH INFLATION. THE NATIONAL HEALTH COUNCIL, WHICH COULD EXPEDITE DRUG REGISTRATIONS, IS STILL NOT FUNCTIONING. FERRER##

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