THOMAS O. HENTELEFF
KINSEY S. REAGAN
PETER R. MATHERS
ANTHONY L. YOUNG
ANNE V. MAHER
BONNIE A. BEAVERS
DANIEL R. DWYER
GLENN E. DAVIS
STACY L. EHRLICH
JENNIFER A. DAVIDSON
STACEY L. VALERIO
CARRIE C. HORN

OF COUNSEL:
WILLIAM J. HARDY

LAW OFFICES
KLEINFELD, KAPLAN AND BECKER, LLP
1140 NINETEENTH STREET, N.W.
WASHINGTON, D. C. 20036-6606
TELEPHONE (202) 223-5120
FACSIMILE (202) 223-5619
www.kkblaw.com

WEST COAST OFFICE:
ONE MARKET STREET
STEUART TOWER, SUITE 1450
SAN FRANCISCO, CA 94105-1313
TELEPHONE (415) 538-0014
FACSIMILE (415) 538-0016

VINCENT A. KLEINFELD
1907-1993

ALAN H. KAPLAN
1930-2001

RICHARD S. MOREY
1938-2006

May 2, 2007

Recd 5/2/07

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

PETITION FOR STAY OF ACTION

On behalf of Purdue Pharma L.P. and its affiliates ("Purdue"), the undersigned submit this petition under 21 C.F.R. §§ 10.35, 314.50(i), 314.52 and 21 U.S.C. § 355(b)(2), and the cases and authorities cited in: (1) the Citizen Petition filed March 13, 2007 on behalf of Purdue (2007P-0093) and (2) the Citizen Petition filed March 30, 2007 on behalf of Ortho-McNeil, Inc. (2007P-0127), requesting that the Commissioner of Food and Drugs stay the potential grant of effective approval of the new drug application ("NDA") for CIP-TRAMADOL ER, a 24 hour extended release oral dosage form of tramadol, reportedly submitted to FDA by Cipher Pharmaceuticals, Inc. ("Cipher") on June 29, 2006.

I. Decision Involved

The potential grant of effective approval by FDA of the NDA for CIP-TRAMADOL ER, a 24 hour extended release oral dosage form of tramadol, reportedly submitted to FDA by Cipher on June 29, 2006.

2007P-0127

PSA 1

II. Action Requested

By this Petition for Stay, the undersigned hereby request that FDA stay any pending action to grant effective approval of the NDA for CIP-TRAMADOL ER until after the Agency has properly considered the issues raised in the above-referenced Citizen Petitions (FDA Dockets 2007P-0093 and 2007P-0127) and has announced its rulings on those issues. To the extent the Agency desires to consider rejecting the Petitions, the stay is requested to remain in effect while the Agency invites public comment on the significant reversal of Agency policy and interpretation that such action would necessarily entail, prior to ruling on the Petitions.

III. Statement of Grounds

A. Introduction

The referenced Citizen Petitions object to the potential approval of Cipher's CIP-TRAMADOL ER product based on an NDA submitted under FFDCA Section 505(b)(2) which apparently (1) fails to include necessary certifications to the Purdue patent listed in connection with the prior approval of NDA # 21-692 (Ultram® ER Tablets) and (2) is subject to an unexpired three-year period of non-patent exclusivity associated with that same NDA approval.[1]

The Petitions rely on FDA's clearly-stated, long-standing interpretation and application of the Hatch-Waxman patent certification and non-patent exclusivity provisions and regulations. Thus, any approval of the CIP-TRAMADOL ER NDA would not only contravene the applicable statutory provisions, but would also entail a direct reversal of existing agency policy. Such action would require an extensive administrative record including an opportunity for public notice and comment on the possibility that FDA would indeed, reverse its previous interpretations and applications of the applicable statutory and regulatory provisions. Here, not only has there been no request by FDA for public comment

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[1] The Purdue Petition 2007P-0093 alternately points out that, if the CIP-TRAMADOL ER NDA purports to have been submitted under FFDCA Section 505(b)(1), then FDA may not approve that NDA unless and until Cipher has included within it all data (or rights to reference data) necessary to establish the safety and effectiveness of the product. However, based on statements made by Cipher on May 2, 2007 (see footnote 2 below), Cipher appears to consider its application to be subject to FFDCA Section 505(b)(2).

on the issues raised in the Petitions, Cipher itself has not even filed a response to either of the Petitions. Thus, at this stage, there is clearly no basis on which FDA could properly even consider denying the Petitions.

In an earnings call on May 2, 2007, Cipher's President, Larry Andrews, stated that the Cipher NDA contained "certifications" only with respect to the previously-approved immediate release version of Ultram®.[2] Under FDA's regulations and rulings on the certification requirements of Hatch-Waxman, such a certification is clearly inadequate to justify approval of the NDA because it leaves out the necessary certifications to the Purdue patent listed in connection with the most similar previously-approved product, *i.e.*, the 24-hour extended release version of Ultram® approved under NDA # 21-692. It is well settled that an agency must engage in notice and comment rulemaking before changing its interpretation of a regulation. *See Environmental Integrity Project v. EPA*, 425 F.3d 992, 997 (D.C. Cir. 2005); *Alaska Prof. Hunters Ass'n v. FAA*, 177 F.3d 1030, 1034 (D.C. Cir. 1999). Similarly, an agency's failure to adhere to its own precedents must be the product of a reasoned analysis that acknowledges and adequately justifies the change. *See Southwestern Elec. Power Co. v. FERC*, 810 F.2d 289, 291 (D.C. Cir. 1987); *Greyhound Corp. v. ICC*, 551 F.2d 414, 416 (D.C. Cir. 1977). Accordingly, whether rejection of the Petitions would entail a change in FDA's interpretation of its regulations or not, an opportunity for public comment is clearly warranted. *See NAACP v. FCC*, 682 F.2d 993 (D.C. Cir. 1982) (change in policy adequately explained by the agency where agency first solicited public comment as to whether the policy should be continued, modified, or repealed).[3]

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[2] A webcast of the earnings call is available at http://www.cipherpharma.com/web-/main.cfm?docID=22. In that same earnings call, Mr. Andrews acknowledged that FDA may decide the CIP-TRAMADOL ER NDA is currently blocked by the 3-year exclusivity applicable to the extended-release version of Ultram®.

[3] The Agency has recently recognized the value of public comments on complex issues associated with the Hatch-Waxman Amendments. *See* Letter from G. Buehler re: amlodipine besylate products (March 29, 2007), available at http://www.fda.gov/ohrms/dockets/dockets-/07n0123/07n-0123-let0001.pdf; CDERWEEK 3/26-30/2007 (Emailed to mailing list at CDERWEEK@LIST.NIH.GOV on April 2, 2007): "Office of Generic Drugs: FDA solicits comments on Amlodipine Abbreviated New Drug Application Approval issues", linking to http://www.fda.gov/ohrms/dockets/dockets/07n0123/07n0123.htm.

B. The Requested Stay Is Fully Justified

Section 10.35(e) of FDA's regulations provides that a stay shall be granted if all of the following criteria are met:

(1) The petitioner will otherwise suffer irreparable injury;
(2) The petitioner's case is not frivolous and is being pursued in good faith;
(3) The petitioner has demonstrated sound public policy grounds supporting the stay; and
(4) The delay resulting from the stay is not outweighed by public health or other public interests.

As described below, each of these criteria is met, and the requested stay should therefore be granted.

Purdue's case is strong and compelling, and denial of this Petition for Stay would cause Purdue irreparable harm. The pending Citizen Petitions are based on simple, straight-forward application of the requirements of the Hatch-Waxman Amendments and corresponding regulations, as well as long-standing FDA interpretation and application of those requirements. Based on these requirements, Purdue has undertaken substantial investments in pursuing approval of another version of a 24-hour oral tramadol product (along with its partner Labopharm) and, in light of the prior approval of Ultram® ER NDA # 21-692, has secured a waiver of the non-patent exclusivity rights associated with that NDA and a right to refer to underlying data in support of the Labopharm product. It took these steps even though the Purdue/Labopharm product was developed completely independently from the Ultram® ER product and, in the absence of the Ultram® ER approval, would not have been blocked by any exclusivity or patent certification rights of any other party. Reversal by FDA of the clear and unambiguous policies that underlay its prior interpretations of the Hatch-Waxman requirements would thus permanently and irreparably reduce the value of Purdue's investment in securing the approvability of a 24-hour tramadol product. Independent of its particular interest in once daily tramadol products, Purdue would also be substantially and irreparably harmed by the Agency's elimination of the reasonable expectations of pioneer drug developers such as Purdue and Ortho-McNeil regarding their patent certification and non-patent exclusivity rights against subsequent applicants for approval of substantially similar drug products. Therefore, assuming that the Agency were to have the right to abruptly contravene and re-define those rights, it is critical that such action be taken only after

following proper procedures and on a complete and adequate administrative record.

For these same reasons, sound public policy requires that the stay requested in this Petition for Stay be granted. Granting of the stay will further the deliberative process by ensuring that the issues raised in the pending Citizen Petitions are fully and carefully considered and that the Agency's existing, long-standing positions are not improperly reversed or contravened. The patent certification and non-patent exclusivity provisions of the Hatch-Waxman Amendments were a critical part of the overall compromise on which the enactment of the statutory ANDA and 505(b)(2) approval processes was based. Preserving those safeguards is thus critical to the continued success of that compromise legislation. For instance, that compromise deprived pharmaceutical patent holders of certain rights available to all other patent holders; namely, the right to prevent infringing uses during the patent term. Specifically, pharmaceutical patent holders lost the right to prevent competitors from the making, using, or selling of an infringing product during the patent term for purposes of obtaining FDA approval. In exchange, patent holders were, through operation of the certification, notice, and automatic 30-month stay provisions, to be afforded the opportunity to resolve patent disputes prior to the approval and market entry of potentially infringing products. Thus, contravening the patent certification requirements of Hatch-Waxman, and their application to 505(b)(2) applicants for drug products that are substantially similar to previously-approved, patented drug products, would reverse the presumption that patent disputes about me-too drugs should be addressed prior to product approval – not in post-approval litigation including, potentially, the need to seek emergency relief from the Courts after an infringing product is approved and threatened to be launched

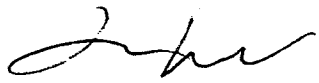
Moreover, any delay resulting from the requested stay is not outweighed by public health or other public interests. Other tramadol products, including Ultram® ER, will continue to be available while the status of Cipher's CIP-TRAMADOL ER NDA is properly considered and resolved. Furthermore, given that the Cipher NDA is still in its first review cycle and Cipher has not even responded to the pending Citizen Petitions, it is not clear whether even Cipher expects an approval of its product in the near future. Even if it did, the fact that Purdue raised the patent certification issues in correspondence with Cipher over seven months ago – and Cipher has thus far chosen to ignore those issues – provides Cipher with no justification to complain that resolution of the issues may now affect the timing of its NDA approval. Finally, Cipher has acknowledged in an April 10, 2007 press release that it "expects the FDA to address [the non-patent

exclusivity] issue in conjunction with its consideration of the Company's anticipated approval." *See* Attachment A. Thus, Cipher is fully aware that issues of patent certification and non-patent exclusivity are, unless addressed by the applicant proactively and in advance, likely to remain issues when other critical reviews have been completed. Therefore, Cipher cannot legitimately complain about a stay while the Agency completes its review of the pending Citizen Petitions as requested in this Petition for Stay.

IV. Conclusion

For the reasons outlined above, the undersigned request that FDA stay any pending action to grant effective approval of the NDA for CIP-TRAMADOL ER until after the Agency has properly considered the issues raised in Citizen Petitions 2007P-0093 and 2007P-0127 and has announced its rulings on those issues and, if the Agency desires to consider rejecting the relief requested in the Petitions, the Agency invites public comment on that potential reversal of agency policy and interpretation prior to ruling on the Petitions.

Respectfully submitted,



Peter R. Mathers
Jennifer A. Davidson
Counsel for Purdue Pharma L.P.

INVESTOR RELATIONS CONTACT:
Craig Armitage
The Equicom Group Inc.
(416) 815-0700 ext. 278
carmitage@equicomgroup.com

FOR IMMEDIATE RELEASE **Toronto Stock Exchange Symbol: DND**

CIPHER PHARMACEUTICALS COMMENTS ON ORTHO-MCNEIL CITIZEN PETITION

MISSISSAUGA, Ontario, April 10, 2007 – Cipher Pharmaceuticals Inc. (TSX: DND) today commented on a Citizen Petition submitted recently to the U.S. Food and Drug Administration (FDA) by Ortho-McNeil, Inc. regarding "tramadol for once-daily dosing." In the Citizen Petition, Ortho-McNeil requests a determination "that any versions of tramadol for once-daily dosing will not be approved prior to expiration of the three-year period of exclusivity for Ultram ER," which expires in September 2008. The Company believes that its New Drug Application for CIP-TRAMADOL ER, an extended-release capsule formulation of the pain medication tramadol, satisfies all statutory and regulatory requirements for approval. The Company has already provided its views to the FDA on the three-year exclusivity, and expects the FDA to address this issue in conjunction with its consideration of the Company's anticipated approval.

About Cipher Pharmaceuticals Inc.

Cipher Pharmaceuticals is a drug development company focused on commercializing novel formulations of successful, currently marketed molecules using advanced drug delivery technologies. Cipher's strategy is to in-license products that incorporate proven drug delivery technologies and advance them through the clinical development and regulatory approval stages, after which the products are out-licensed to international partners. Because Cipher's products are based on proven technology platforms applied to currently marketed drugs, they are expected to have lower approval risk, shorter development timelines and significantly lower development costs. Cipher currently has three late-stage drugs in its pipeline. The Company's lead compound, CIP-FENOFIBRATE, received final approval from the U.S. Food and Drug Administration and Health Canada in the first quarter of 2006. In addition, Cipher is developing formulations of the pain reliever tramadol (currently under regulatory review by the FDA) and the acne treatment isotretinoin (currently under regulatory review by the FDA).

Cipher is listed on the Toronto Stock Exchange under the symbol 'DND' and has approximately 24 million shares outstanding. For more information, please visit www.cipherpharma.com.

Forward-Looking Statements

Statements made in this news release, other than those concerning historical financial information, may be forward-looking and therefore subject to various risks and uncertainties. Some forward-looking statements may be identified by words like "may", "will", "anticipate", "estimate", "expect", "intend", or "continue" or the negative thereof or similar variations. Certain material factors or assumptions are applied in making forward-looking statements and actual results may differ materially from those expressed or implied in such statements. Factors that could cause results to vary include those identified in the Company's Annual Information Form and other filings with Canadian securities regulatory authorities, such as the applicability of patents and proprietary

technology; possible patent litigation; regulatory approval of products in the Company's pipeline; changes in government regulation or regulatory approval processes; government and third-party payer reimbursement; dependence on strategic partnerships for product candidates and technologies, marketing and R&D services; meeting projected drug development timelines and goals; intensifying competition; rapid technological change in the pharmaceutical industry; anticipated future losses; the ability to access capital to fund R&D; and the ability to attract and retain key personnel. All forward-looking statements presented herein should be considered in conjunction with such filings. The Company does not undertake to update any forward-looking statements; such statements speak only as of the date made.

For more information, please contact:

Craig Armitage
Investor Relations
The Equicom Group
(416) 815-0700 ext 278
(416) 815-0080 fax
carmitage@equicomgroup.com

Larry Andrews
President & Chief Executive Officer
Cipher Pharmaceuticals
(905) 602-5840 ext 24
(905) 602-0628 fax
landrews@cipherpharma.com

INVESTOR RELATIONS CONTACT:
Craig Armitage
The Equicom Group Inc.
(416) 815-0700 ext. 278
carmitage@equicomgroup.com

FOR IMMEDIATE RELEASE

Toronto Stock Exchange Symbol: DND

CIPHER PHARMACEUTICALS COMMENTS ON PURDUE PHARMA CITIZEN PETITION

MISSISSAUGA, Ontario, March 15, 2007 – Cipher Pharmaceuticals Inc. (TSX: DND) ("Cipher" or "the Company") today commented on a "Citizen Petition" submitted yesterday to the U.S. Food and Drug Administration (FDA) by Purdue Pharma L.P. regarding Cipher's New Drug Application (NDA) for CIP-TRAMADOL ER, an extended-release capsule formulation of the pain medication tramadol. The six-page Citizen Petition contains allegations regarding the appropriate reference listed drug and patent certification for the Company's NDA, and whether the NDA should be approved as submitted. The Company believes that these allegations and the Citizen Petition are baseless and without merit, and that the Company's NDA satisfies all statutory and regulatory requirements for approval.

About Cipher Pharmaceuticals Inc.

Cipher Pharmaceuticals is a drug development company focused on commercializing novel formulations of successful, currently marketed molecules using advanced drug delivery technologies. Cipher's strategy is to in-license products that incorporate proven drug delivery technologies and advance them through the clinical development and regulatory approval stages, after which the products are out-licensed to international partners. Because Cipher's products are based on proven technology platforms applied to currently marketed drugs, they are expected to have lower approval risk, shorter development timelines and significantly lower development costs. Cipher currently has three late-stage drugs in its pipeline. The Company's lead compound, CIP-FENOFIBRATE, received final approval from the U.S. Food and Drug Administration and Health Canada in the first quarter of 2006. In addition, Cipher is developing formulations of the pain reliever tramadol (currently under regulatory review by the FDA) and the acne treatment isotretinoin (currently under regulatory review by the FDA).

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changes in government regulation or regulatory approval processes; government and third-party payer reimbursement; dependence on strategic partnerships for product candidates and technologies, marketing and R&D services; meeting projected drug development timelines and goals; intensifying competition; rapid technological change in the pharmaceutical industry; anticipated future losses; the ability to access capital to fund R&D; and the ability to attract and retain key personnel. All forward-looking statements presented herein should be considered in conjunction with such filings. The Company does not undertake to update any forward-looking statements; such statements speak only as of the date made.

For more information, please contact:

Craig Armitage
Investor Relations
The Equicom Group
(416) 815-0700 ext 278
(416) 815-0080 fax
carmitage@equicomgroup.com

Larry Andrews
President & Chief Executive Officer
Cipher Pharmaceuticals
(905) 602-5840 ext 24
(905) 602-0628 fax
landrews@cipherpharma.com